Law Reform Commission

Compensation of Vaccine-Damaged Children

2000

Manitoba

Law Reform Commission

Commission de réforme du droit

100-06892/

COMPENSATION OF VACCINE-DAMAGED CHILDREN

Report #104

June 2000

Canadian Cataloguing in Publication Data

Manitoba. Law Reform Commission.

Compensation of vaccine-damaged children

(Report ; #104)

Includes bibliographical references.
ISBN 0-7711-1513-X

1. Vaccination -- Complications -- Manitoba. 2. Vaccination -- Complications. 3. Vaccination of children -- Complications -- Manitoba. 4. Vaccination of Children -- Complications. 5. Compensation (Law) -- Manitoba. 6. Compensation (Law). I. Title. II. Series : Report (Manitoba. Law Reform Commission) ; #104

KE3589.M36 2000 614.47'097127 C00-962009-5

Some of the Commission's earlier Reports are no longer in print. Those that are still in print may be ordered from the Publications Branch, 200 Vaughan Street, Winnipeg, Manitoba R3C 1T5

The Manitoba Law Reform Commission was established by *The Law Reform Commission Act* in 1970 and began functioning in 1971.

Commissioners:

Clifford H.C. Edwards, Q.C., *President*
John C. Irvine
Hon. Mr. Justice Gerald O. Jewers
Hon. Pearl K. McGonigal
Kathleen C. Murphy

Administrator:

Suzanne Pelletier

The Commission offices are located at 1210-405 Broadway, Winnipeg, Manitoba R3C 3L6. TEL. (204) 945-2896, FAX (204) 948-2184, E-mail: lawreform@jus.gov.mb.ca
Website: http://www.gov.mb.ca/justice/mlrc/

The Manitoba Law Reform Commission is funded by grants from:

The Government of Manitoba

and

The Manitoba Law Foundation

TABLE OF CONTENTS

		Page #
CHAPTER 1 - INTRODUCTION		1
A.	THE ISSUE	1
B.	THE SCOPE OF THE REPORT	2
C.	ACKNOWLEDGEMENTS	2
CHAPTER 2 - THE STRUCTURE OF THE MANITOBA CHILDHOOD IMMUNIZATION PROGRAM		3
A.	FEDERAL GOVERNMENT	3
B.	MANITOBA	4
CHAPTER 3 - VACCINE INJURIES AND THE ACCIDENT COMPENSATION SYSTEM OF MANITOBA		8
A.	CIVIL LIABILITY (THE TORT SYSTEM)	8
	1. Health Care Professionals	8
	(a) Administration of the vaccine	9
	(b) Informed consent	9
	2. Manufacturers	10
	(a) Defective manufacture	11
	(b) Failure to warn	11
	(c) Defective design	12
	3. Access to the Tort System	12
B.	GOVERNMENTAL COMPENSATION SYSTEMS	13
C.	PRIVATE PROTECTION	13
CHAPTER 4 - THE CASE FOR THE NO-FAULT COMPENSATION OF CHILDHOOD VACCINE INJURIES		15
CHAPTER 5 - VACCINE COMPENSATION SCHEMES IN OTHER JURISDICTIONS		17
A.	QUÉBEC	17
	1. Introduction	17
	2. The Compensation Plan	18
	3. Vaccines Covered	18
	4. Compensable Injuries	18
	5. Compensation	19
	6. Procedures	19
	7. Appeals	20
	8. Funding	21
	9. Limitations	21

10. Tort Claims 21
11. Retroactive Claims 21
12. Claims Experience 21
13. Miscellaneous 21

B. UNITED STATES 22
1. Introduction 22
2. The Compensation Plan 22
3. Vaccines Covered 23
4. Compensable Injuries 23
5. Compensation 24
6. Procedures 24
7. Appeals 25
8. Funding 25
9. Limitations 25
10. Tort Claims 25
11. Retroactive Claims 26
12. Claims Experience 26
13. Miscellaneous 26

C. UNITED KINGDOM 27
1. Introduction 27
2. The Compensation Program 27
3. Vaccines Covered 27
4. Compensable Injuries 27
5. Compensation 28
6. Procedures 28
7. Appeals 28
8. Funding 28
9. Limitations 28
10. Tort Claims 29
11. Retroactive Claims 29
12. Claims Experience 29
13. Miscellaneous 29

D. NEW ZEALAND 29
1. Introduction 29
2. The Compensation Program 30
3. Vaccines Covered 30
4. Compensable Injuries 30
5. Compensation 31
6. Procedures 31
7. Appeals 31
8. Funding 32
9. Limitations 32
10. Tort Claims 32

11. Retroactive Claims 32
12. Claims Experience 32

CHAPTER 6 - RECOMMENDATIONS FOR A MANITOBA CHILDHOOD VACCINATION INJURY COMPENSATION PLAN 33
A. INTRODUCTION 33
B. THE COMPENSATION PLAN 33
C. VACCINES COVERED 34
D. COMPENSABLE INJURIES 35
E. COMPENSATION 36
F. PROCEDURES 37
G. APPEALS 38
H. FUNDING 38
I. LIMITATIONS 39
J. TORT CLAIMS 39
K. RETROACTIVE CLAIMS 40
L. ADDITIONAL ISSUES 41
1. Informed Consent 41
2. Reporting of Adverse Events 42

CHAPTER 7 - LIST OF RECOMMENDATIONS 44

APPENDIX A- COMPARISON OF EFFECT OF DISEASES AND VACCINES 47

APPENDIX B - REPORT OF A VACCINE-ASSOCIATED ADVERSE EVENT 49

APPENDIX C - MANITOBA IMMUNIZATION SCHEDULE 53

APPENDIX D - VACCINE INJURY COMPENSATION PROGRAMS WORLDWIDE 57

APPENDIX E - *AUTOMOBILE INSURANCE ACT*, R.S.Q. c. A-25 59

APPENDIX F - NATIONAL VACCINE INJURY COMPENSATION PROGRAM: VACCINE INJURY TABLE 65

APPENDIX G - NATIONAL VACCINE INJURY COMPENSATION PROGRAM: MONTHLY STATISTICS REPORT 73

APPENDIX H - *THE MANITOBA PUBLIC INSURANCE CORPORATION ACT*, C.C.S.M. c. P215 76

APPENDIX I - NEW BRUNSWICK IMMUNIZATION PROTOCOL 81

EXECUTIVE SUMMARY 85

RÉSUMÉ 91

CHAPTER 1

INTRODUCTION

This project was initiated by a member of the Commission, Prof. John Irvine, and in response to a request from the Association for Vaccine-Damaged Children.

A. THE ISSUE

Routine childhood immunization is a cornerstone of public health practice in Canada. It has received the strong support of government, the medical profession and the great majority of the public. It has achieved much success in the reduction of many childhood illnesses including polio, diphtheria, whooping cough, mumps and measles.

The characteristics of an ideal vaccine have been identified in the *Canadian Immunization Guide*.[1] The vaccine should confer long-lasting protection against disease, be administered in few doses, be inexpensive enough for wide-scale use, be stable enough to remain potent during shipping and storage and have *no adverse effect on the recipient*. This Report deals with the failure to achieve fully the last of these objectives. In spite of the efforts of medical science, manufacturers and physicians, vaccines sometimes have side effects. Adverse consequences may be suffered by the recipients of vaccines. The conventional wisdom is that most of these consequences are minor and short term. Some tenderness and redness may be experienced at the site of the vaccination and the child may have a low fever. In exceptional circumstances, the consequences may be serious, such as high fever, systemic joint or muscle pain, seizures or anaphylactic shock. In rare situations, a child may suffer permanent disability such as neurological damage, or may even die. A chart found in the *Canadian Immunization Guide* comparing some of the effects of vaccines and the diseases they are intended to prevent is reproduced in Appendix A. It reflects the current opinion of Health Canada.

The extent to which vaccines cause serious adverse consequences is, however, a matter of considerable debate both inside and outside the medical profession. There is extensive literature on the subject[2] and strong opinions are held. The situation is further complicated by both the difficulty in distinguishing between conditions that are *temporally related* to the administration of the vaccine and conditions that are *caused* by the vaccine and by the fact that the system of routine childhood vaccination is not static. New vaccines are periodically

---

[1] *Canadian Immunization Guide* (5th ed., 1998) 1.

[2] The current scientific thinking on the nature and extent of adverse consequences of particular vaccines is found in the *Canadian Immunization Guide*, *id.*

introduced and old vaccines are replaced with improved products. The attenuated whole cell pertussis vaccine has, for example, been replaced with an acellular vaccine which may have fewer serious side effects. Nevertheless, some parents are sufficiently alarmed by the risk of immunization to refuse to immunize their children. The debate about the extent and seriousness of adverse vaccine consequences is one that this Report does not enter. It is beyond the expertise and resources of the Manitoba Law Reform Commission even to comment on it, let alone resolve it.

The purpose of this Report is to make recommendations in respect of the compensation of children who can establish that they *have* suffered serious, adverse consequences as a result of a vaccination or a series of vaccinations. It will be shown that the existing public and private vehicles for the compensation of personal injury are insufficient to provide the financial support needed by those who suffer rare but serious consequences. Special measures are needed to support and assist them.

B. SCOPE OF THE REPORT

The Report begins by outlining in summary fashion the structure of the Manitoba system of childhood vaccination. It goes on to consider available remedies and compensation currently available for vaccine-injured children. Reference is then made to the special claim these children have for special and favourable treatment. Consideration is then given to the experience in some other jurisdictions that have made special provision for compensation in these cases. Finally, the range of issues pertaining to a targeted and discrete compensation system for vaccine-injured children is reviewed and recommendations are made.

C. ACKNOWLEDGEMENTS

Although the initial reference was received in late 1996, the project did not get underway until early 1999 due to lack of resources. However, our requests for grants from the Manitoba Law Foundation to cover the cost of consultancy fees and from the Province of Manitoba to cover the administrative costs were both approved for the fiscal year 1999-2000. We are most grateful to the Foundation and the Department of Health for their support of this project. As a result, we were able to retain the services of Prof. Philip H. Osborne of the Faculty of Law, University of Manitoba, to undertake the project and prepare this Report. His assistance in guiding us through the difficult policy issues addressed in the Report was invaluable and we extend our most sincere thanks. We also wish to thank Lee Ann Martin and Bonnie Macdonald, legal research assistants, who undertook the legal and empirical research during the conduct of the project and who updated the figures in the Québec and Manitoba charts for the final report, respectively.

We would also like to acknowledge the assistance of Ms Nadine Tremblay of the Public Health Protection Branch, Department of Health and Social Services, Québec, and Dr. G. Evans, Medical Director, National Vaccine Injury Compensation Program, United States.

CHAPTER 2

THE STRUCTURE OF THE MANITOBA CHILDHOOD IMMUNIZATION PROGRAM

The structure and implementation of the system of childhood immunization in Manitoba is the responsibility of the provincial government. Nevertheless, the federal government plays an important role in the support, consistency and integrity of all provincial and territorial programs and it is useful to identify some of those contributions before narrowing the focus to the current Manitoba system.[1]

A. FEDERAL GOVERNMENT

Canada is a signatory to the *Declaration of the 1990 World Summit for Children* which establishes goals for the eradication and reduction of diseases in children. The federal government has been involved in establishing national goals and targets through both the Laboratory Centre for Disease Control and the Health Services and Promotion Branch of Health Canada.

Manufacturers of vaccines must secure from the federal government a licence to market any vaccine in Canada. The licence is issued by the Bureau of Biologics and Radiopharmaceuticals of the Health Protection Branch, Health Canada. Provincial and territorial governments purchase licensed vaccines which are administered free of charge to children.

The National Advisory Committee on Immunization provides recommendations for the optimal childhood immunization programs in terms of types of vaccines, their dosages, the age of the child when various vaccines should be given, the storage of vaccines and the general administration of the immunization program. The members of the Committee are experts in public health, infectious diseases and pediatrics. Their recommendations are contained in the *Canadian Immunization Guide*. As a general rule their recommendations and their other periodic statements on vaccine use are followed by provincial governments.

The federal government also plays a significant role in the surveillance of vaccines and immunization programs for adverse consequences. It is responsible, through the Laboratory Centre for Disease Control, for the VAAE (Vaccine Associated Adverse Events) system. It relies on a system of voluntary reporting to monitor the safety of the immunization programs. Local health care providers may report to the provincial or territorial public health authorities events that they believe are temporally related to the administration of a vaccine. Only in Ontario is

---

[1] A great deal of the information for this Chapter was drawn from the *Canadian National Report on Immunization, 1996*, found through the Health Canada Web Site at http://www.hc-sc.gc.ca/hpb/lcdc/publicat/ccdr/97vol23/imm_sup/index.html

that they believe are temporally related to the administration of a vaccine. Only in Ontario is reporting mandatory[2]. These reports are then forwarded to the Immunization Division of the Laboratory Centre for Disease Control for computerized compilation and analysis. In 1994, a multi-disciplinary advisory group was formed (Advisory Committee on Causality Assessment) to review the most serious cases (death, seizures without fever and neurological reactions) for study. They look at the likelihood of the reaction being caused by a vaccination and identify potential side effects. Recommendations may be made for further research or for some change in the immunization program. The *Canadian Immunization Guide* provides information about adverse effects of vaccines and also contains a model Reporting Form (see Appendix B).

The VAAE system is supplemented by the IMPACT surveillance system. This is an active surveillance system which operates in 11 pediatric health care facilities across Canada (including the Health Sciences Centre in Winnipeg) accounting for 80% of all tertiary-care admissions in the country. Each centre actively looks for cases of serious vaccine-related events and illnesses. A third initiative is the Canadian Paediatric Surveillance Program under which practising paediatricians report on selected vaccine-associated adverse events.

B. MANITOBA

The structure and implementation of the childhood immunization program is a provincial responsibility. The Public Health Branch of Manitoba Health in consultation with the Manitoba Advisory Committee on Infectious Diseases determines which vaccines should be administered in the province and to whom they should be administered. Normally the recommendations of the National Advisory Committee on Immunization are followed. Manitoba Health then makes a request to Treasury Board to fund the administration of the vaccine to the target group. When approval is secured Manitoba Health, in due course, informs physicians of the availability of the vaccine.

Currently the vaccines available and recommended for the *routine* immunization of children in Manitoba are DaPTP (diphtheria, acellular pertussis, tetanus, inactivated polio), Hib (haemophilus influenzae B [PRP-T]), MMR (measles, mumps, rubella), Td (tetanus; adult diphtheria formulation), IPV (inactivated polio) and Hep B (hepatitis B). Additional vaccines such as Varivax, to prevent chickenpox, may be added in the future.[3] Other vaccines such as BcG (tuberculosis),[4] pneumococcal and meningococcal vaccines may be administered in special circumstances. Physicians may also provide vaccines such as hepatitis A, Japanese encephalitis

---

[2]*Health Protection and Promotion Act*, R.S.O. 1990, c. H.7, s. 38(2).

[3]It has been recommended by the National Advisory Committee on Immunization for children under 13. It was discussed at the National Varicella Consensus Conference in May 1999. There is some concern about the stability of the current vaccine in storage and some health care professionals and members of the public have reservations about its value

[4]BcG is provided to children born on or living on reserves.

and Lyme disease which are not funded by government.

The vaccination of children is not compulsory in Manitoba. The decision to vaccinate or not to vaccinate is left to parents or guardians to be made by them in consultation with their medical advisers. Until recently proof of immunization was a pre-requisite to first time admission to school.[5] Exemptions were available where a parent or guardian provided a written statement of belief that immunization was prejudicial to health or was contrary to the religious beliefs of the parent or guardian. This provision alerted parents and guardians to the immunization status of their child and placed some mild coercion on parents to secure appropriate vaccination so as to avoid the need to make a formal declaration on medical or religious grounds. In 1999, that provision was repealed.[6]

It should be noted that there is a conditional power to order a person to be vaccinated under *The Public Health Act*.[7] It authorizes a medical officer, in the case of an epidemic or threatened epidemic of a communicable disease, to order a person to be vaccinated *unless* the person makes a written declaration that a vaccination would be prejudicial to his or her health or would be against his or her religious beliefs.

In Manitoba, most childhood immunizations (around 75%) are provided to children by their physicians. Most of the others are given by public health nurses and a few are given in hospitals. Vaccinations given by public health nurses are common in northern and rural areas of the province. Public health nurses also provide measles and hepatitis B vaccines through a school-based program.

The standard practice is to provide a series of recommended vaccinations beginning in infancy. Routine immunization is, in large part, completed by age 9-10 (Hep B). The Td vaccination, given at age 15, is the exception. Children who are not immunized in infancy may be given some of the routine vaccinations at a later date. The Manitoba Schedule of Routine Immunization is found in Appendix C. It has been recommended that each child should receive a permanent personal immunization record and the vaccine provider should maintain a permanent record of the immunization history of each child. The latter record should include the trade name of the product, the date on which the vaccination was given, the dosage, the site and route of administration, the manufacturer's lot number of the vaccine and the name of the person who gave the vaccination.[8]

The operation of the childhood immunization system in Manitoba is monitored by the

---

[5] *The Public Schools Act*, R.S.M. 1987, c. P250, s. 261(1).

[6] *The Public Schools Amendment Act*, S.M. 1999, c. 14 s. 5.

[7] *The Public Health Act*, C.C.S.M. c. P210, ss. 12 and 32.

[8] *Canadian Immunization Guide* (5th ed., 1998) 51.

Manitoba Immunization Monitoring System (MIMS), a centralized computer registry which records the immunization history of children in the province.[9] All children who live in Manitoba and were born after January 1, 1980 are automatically registered in MIMS through the Manitoba Health registry system.[10] Each child has attached to his or her name a list of immunizations that have been received. This allows Manitoba Health to identify those children who, at school age, have an incomplete immunization record. Manitoba Health has adopted a pro-active role in seeking to insure that the children with an incomplete record are fully vaccinated. In cooperation with the Department of Education, vaccinations are administered in the schools by public health nurses. There is also a school-based vaccination program offering measles and Hepatitis B vaccinations. Parental consent is, of course, still required. Some parents may prefer that all vaccinations be given by their physician. Others refuse to complete the vaccinations on a variety of grounds including a belief that it unduly threatens the health of their child or is inconsistent with their religious beliefs.

Unlike Ontario,[11] Manitoba relies on a *voluntary* system of reporting adverse reactions to vaccinations. Health care professionals providing vaccinations are encouraged to report all vaccine adverse events. They are reported to the local medical officer of health, who determines if further vaccination should be continued, and to Manitoba Health. From Manitoba Health they are sent to the Division of Immunization of the Laboratory Centre for Disease Control of Health Canada for entry into the VAAE data base. The most serious cases are studied by the Advisory Committee of Causality Assessment.

The integrity and viability of any immunization system depends upon the informed support of the participating public. It is essential that information of the benefits and risks of immunization together with information of the risks and consequences of the disease that the vaccination seeks to prevent are provided in a clear and comprehensive manner. Vaccine providers should also provide an opportunity for parents to ask questions and seek information. The obligation to secure an informed consent to vaccinations is recognized at *common law*[12] and that duty is familiar to most physicians. There is, however, no *legislative* requirement, similar to

---

[9]A description of the system is found in the *Manitoba Immunization Monitoring System (MIMS): Annual Review 1997*, a publication of Communicable Disease Control, Public Health Branch, Manitoba Health.

[10]A national registry akin to MIMS is in the planning stage. At the Canadian Consensus Conference on a National Immunization Records System in March of 1998, a plan for a Nationwide Immunization Records Network was developed. The goal is for every province and territory to have a comprehensive electronic immunization registry capable of participating in a nationwide immunization records network within five years. These registries would share common data standards and have the capacity for inter-provincial exchange of records. The registries would focus initially on childhood vaccination.

[11]*Health Protection and Promotion Act*, R.S.O. 1990, c. H. 7, s. 38(3). In 1992, a Private Member's Bill, modelled on the Ontario legislation calling for mandatory reporting of certain temporally related conditions following vaccination, was introduced into the Manitoba Legislature. Bill 209, *The Public Health Amendment Act*, 4th session, 35th Legislature, 41 Eliz. II, 1992, was not passed. Other attempts to pass similar Bills at future sessions have also failed [see, e.g. Bill 216, *The Public Health Amendment Act*, 6th session, 35th Legislature, 43 Eliz. II, 1994].

[12]*Reibl* v. *Hughes*, [1980] 2 S.C.R. 880.

that found in section 38(2) of the *Health Protection and Promotion Act* of Ontario, that a health care professional inform a vaccine recipient of the risks of a vaccination.[13] Manitoba Health assists in the educational process with a variety of brochures and pamphlets describing the process of routine childhood vaccination and the risk of adverse side effects.

The *Manitoba Immunization Monitoring System (MIMS): Annual Review 1997* analyzed vaccination rates in the province for the years 1993-1995. Vaccination rates are around 75% of the target population. This is well below the optimum rate of 95% set by Health Canada.

[13] *Health Protection and Promotion Act*, R.S.O. 1990, c. H.7. In 1992, a Private Member's Bill was introduced in Manitoba modelled on the Ontario legislation creating a statutory duty to secure an informed consent before administering a vaccine. Bill 209, *The Public Health Amendment Act*, 4th session, 35th Legislature, 41 Eliz. II, 1992, was not passed. Other attempts to pass similar Bills at future sessions have also failed [see, e.g. Bill 216, *The Public Health Amendment Act*, 6th session, 35th Legislature, 43 Eliz. II, 1994].

CHAPTER 3

VACCINE INJURIES AND THE ACCIDENT COMPENSATION SYSTEM OF MANITOBA

The Manitoba system of compensation for injuries, illness or death caused by accidental conduct is an amalgam of civil liability (tort liability), governmental no-fault schemes, social welfare programs and private first party insurance. None of these programs provides adequate compensation for death, illness or injuries caused by the administration of vaccines. Each aspect of the compensatory system will be considered in turn.

A. CIVIL LIABILITY (THE TORT SYSTEM)

The law of torts imposes a personal liability on persons who cause death, illness or injuries as a consequence of their wrongful conduct. The remedy is an award of damages which is designed to place the victim in the position he or she was in before the accident occurred insofar as money can achieve that goal.

The tort of *negligence* is of particular relevance to vaccine-related disability. The tort of negligence imposes liability for damage caused by the failure of one person (the defendant) to take reasonable care for the safety of another person (the plaintiff). The plaintiff must prove that the defendant owed the plaintiff a legal duty of care and failed to exercise reasonable care so causing foreseeable damage to the plaintiff. The defendant may then be able to assert one or more of the defences of voluntary assumption of risk, which is a complete defence, or contributory negligence which reduces damages in proportion to the plaintiff's responsibility for the damage or the loss. Those who suffer vaccine-related disabilities may have a negligence claim against the person who administered the vaccine such as a physician or a public health care nurse and/or the manufacturer of the vaccine.

1. Health Care Professionals

Those who administer a vaccine, whether they be physicians or nurses, owe a duty of care to the vaccine recipient. This duty has two aspects. First, there is a duty to give the vaccination with reasonable care and skill and in accordance with standard medical practice. Secondly, there is a duty to provide the recipient or, in the case of children, their parents or guardians with sufficient information about the material risks and side effects of the vaccine to secure an informed consent to the procedure.

(a) Administration of the vaccine

A vaccination must be given with reasonable care and in accordance with accepted medical practice, standards and customs. Health care professionals are not guarantors of a patient's safety or well-being. The standard of conduct is not perfection but *reasonable* care. Negligence can arise in a number of ways. The vaccine may be improperly stored or prepared. The vaccination may be given at the wrong site. It may be given at the wrong age. The wrong dosage may be given. The correct timing between vaccine dosages may not be followed. Vaccinations may be contra-indicated because of the health of the child. A course of vaccinations may be continued in spite of adverse reactions exhibited by the child to each of the preceding doses. This allegation is made in the statements of claim of seriously disabled children in the cases of *Dignazio* v. *Weizman*[1] and *Graham* v. *Jamieson*,[2] both of which are pending before the Manitoba Court of Queen's Bench.

The plaintiff must also establish a causal link between the negligent act and the injury. This is a factual inquiry. Cause is found where the injury would not have occurred *but for* the defendant's wrongful act.

Cases of this kind are no different from other medical malpractice actions and they present no particular legal difficulties. It is uncommon, however, for litigation of this kind to arise from the administration of vaccines. The procedures are well known, standardized and routine and the consequences of a lapse in the standard of care are, in most cases, unlikely to be serious.

(b) Informed consent

The health care professional who is giving the vaccine must secure an *informed consent* from the parent or guardian of the child or, in the case of a *mature minor* (i.e. one who understands the nature and risk of the medical procedure), from the recipient.[3] All questions and requests for information must be addressed fully and forthrightly.

A health care professional is required to disclose all material risks of any medical treatment and procedures. Material risks are those which a reasonable person in the position of the patient would want to know when deciding whether or not to consent to the medical procedure at issue. Courts are not reluctant to label risks as 'material' and even very low risks of serious consequences are material for the purposes of negligence law. The information may be given verbally to the patient or use may be made of written brochures and pamphlets. Ultimately,

---

[1] *Dignazio* v. *Weizman*, Manitoba Court of Queen's Bench, File #CI 95-01-94150.

[2] *Graham* v. *Jamieson*, Manitoba Court of Queen's Bench, File #CI 99-01-11655.

[3] The consent of the recipient may be necessary for the Td (tetanus and adult diphtheria) vaccine, routinely given at age 15.

however, the health care professional is obliged to see that the requisite information has been communicated and understood. Undue reliance on written brochures is, therefore, dangerous. The extent and degree of disclosure of the risks of vaccines is high because the recipient is not ill. The cost-benefit ratio to be considered by the consent giver is between the risks of the vaccine and the risks of future illness which the recipient may not, even in the absence of vaccination, incur. In respect of vaccines, therefore, most risks, including common risks of moderate severity and rare risks of grave consequences, must be disclosed.

The more difficult hurdle in respect of informed consent is causation. It has two aspects. First, it must be established by the plaintiff on the balance of probabilities that the injuries suffered were caused by the vaccine. This is a very difficult task. The case of *Rothwell* v. *Raes*[4] is illustrative. The plaintiff, Patrick Rothwell, alleged that the pertussis vaccine caused serious and permanent mental and physical disability. A broad range of expert testimony and medical research was canvassed by the trial judge. The Court held that the plaintiff had not established on the balance of probabilities either that the pertussis vaccine was capable of causing injury of the kind suffered by the plaintiff or, if it was capable of causing such injuries, that it had done so in the case under consideration. (This finding was fatal to the variety of claims made by the plaintiff against the physicians, the manufacturer and the government.) The second aspect of causation relates to the hypothetical response of the parent or mature minor had the appropriate disclosure of information been made by the defendant. It must be shown that the decision maker would have refused to consent to the vaccination if the required information of material risks had been given. However, this question is resolved, not on the basis of what the individual decision maker would have done if he or she was given the information, but on what a *reasonable person* in the particular circumstances of the decision maker would have done. If the same decision would have been made and the same vaccine administered on the same day, the lack of information (the lack of informed consent) did not *cause* the injury or illness. It will be recognized that in almost all situations a full explanation of the risks and benefits of vaccination and the risks and consequences of the disease it is designed to prevent will lead reasonable persons to proceed with the vaccination. Most cases of informed consent in the area of vaccinations will fail on one or other of the causation hurdles.

2. Manufacturers

The manufacturers of vaccines owe a duty of care to the consumers of their products. Liability depends upon proof of negligence. There is no strict liability of manufacturers similar to that in the United States. Negligence may be found in the manufacture of defective vaccines, in the failure to provide information about inherent risks of the vaccine and in the faulty design of vaccines.

---

[4] *Rothwell* v. *Raes* (1988), 54 D.L.R. (4th) 193 (Ont. H.C.J.), aff'd (1990), 76 D.L.R. (4th) 280 (C.A.).

(a) Defective manufacture

Negligence in the manufacture of a vaccine encompasses errors or defects in the production process and/or a failure in the manufacturer's quality control systems. For one reason or another, the vaccine is not compliant with its intended specifications and quality. The vaccine may be contaminated or adulterated with a foreign substance, it may be improperly configured, it may be erroneously labelled or there may be a failure of cold storage. The manufacturer does not, however, guarantee the quality of the vaccine to the recipient. Liability is based on the failure of the manufacturer to attain the standard of reasonable care. Nevertheless, courts are not reluctant to find liability where a vaccine is defective in some way. A loose inference may be drawn that vaccine *defects* are the likely consequence of the manufacturer's failure to take care. Additionally, the plaintiff must prove that his or her illness or injury was *caused* by the defective vaccine.

(b) Failure to warn

A manufacturer of products is under a duty to inform consumers of dangers and risks that it knows or ought to know are inherent in the use of its products.[5] There are, however, practical difficulties in communicating information to the vaccine recipient or his or her decision maker. The patient relies on the health care provider with whom he or she is in direct contact rather than the manufacturer. The Supreme Court of Canada has therefore adopted the *learned intermediary rule*.[6] Under this rule, the vaccine manufacturer may discharge its obligation to provide information to the recipient by giving the information to a learned intermediary (the attending health care professional) who administers the vaccine. The information will then be transmitted to the patient by the learned intermediary. The information is usually provided by the manufacturer in informational inserts and brochures accompanying the vaccine. The manufacturer must supply full and complete information as to risks, side-effects and contra-indications of the vaccine that are known or ought to be known at the time of manufacture. Pertinent information which subsequently becomes known should also be communicated to learned intermediaries.

Once again causation presents a difficult hurdle for plaintiffs alleging injuries and illnesses arising from uninformed risks of the vaccine. It must be proved not only that the vaccine caused the disability but also that the decision maker would have declined to authorize the vaccine if the appropriate information had been passed on by the learned intermediary. In this situation, however, the test is a subjective one. The decision maker must prove on the balance of probabilities that he or she would have refused the vaccine if disclosure of the risks had been made. The manufacturer is not, however, able to exonerate itself on the grounds that had it given the information to the health care professional, it would not have been passed on to the plaintiff.

---

[5] *Lambert* v. *Lastoplex Chemicals Co. Ltd. and Barwood Sales (Ontario) Ltd.*, [1972] S.C.R. 569.

[6] *Hollis* v. *Dow Corning Corp.*, [1995] 4 S.C.R. 634.

Nevertheless the burden of proof on the plaintiff in cases such as these is a difficult one to discharge. In *Rothwell*, for example, the plaintiff established the negligence of the manufacturer on the grounds that insufficient information of possible risks of the pertussis vaccine had been given to physicians. That claim, however, failed on the lack of causation.

(c) Defective design

All manufacturers are under a duty to design a product that is reasonably safe. Defective design cases raise difficult issues which are normally resolved on risk/benefit calculation. Consideration is given to all the relevant circumstances including the benefit of the product, the risks involved, the availability of a safer design, and the risks and benefits of that alternative design. The ultimate question is whether the product is unreasonably dangerous. Given the benefit of vaccines, the rarity of known risks, and the general willingness of the industry to invest in research, to develop and market safer vaccines when they are tested and licensed suggests that establishing liability is very difficult. In *Rothwell*, the plaintiff unsuccessfully alleged that the vaccine in question was poorly designed.

3. Access to the Tort System

Some indication has been given of the difficulty of establishing negligence liability against either a health care professional or a manufacturer. This is borne out by the dearth of reported cases and the lack of success of vaccine-damaged plaintiffs in Canada to date. This situation is exacerbated by procedural and financial obstacles which do not make the tort process conducive to the prompt and efficient handling of vaccine claims. The tort process is plagued by complexity, uncertainty, delay and expense. *Rothwell* v. *Raes*,[7] the leading reported case on vaccine injuries, is illustrative. The trial judgment in favour of the defendants was not rendered until nine years after the vaccine in question was given. An appeal to the Ontario Court of Appeal was dismissed two years later. At trial, there were 50 witnesses who testified for 74 days. It has been estimated that the legal costs of the *Rothwell* litigation exceeded $1,000,000.[8] The delay inherent in the tort process is also illustrated by the two cases pending before the Manitoba Court of Queen's Bench. In *Dignazio* v. *Weizman*, the vaccine was given in 1992. The statement of claim was issued in 1995. The case has yet to come to trial. In *Graham* v. *Jamieson*, the vaccine was given in 1992 and the statement of claim was filed in 1999.

The conclusion is unavoidable. It was drawn by the trial judge in *Rothwell*. He stated: ". . . the normal process of litigation is an utterly inappropriate procedure for dealing with claims

---

[7] *Rothwell* v. *Raes*, *supra* n. 4.

[8] *Rothwell* v. *Raes*, *supra* n. 4, at 354.

of this nature."[9] In practical terms, the tort process holds out very little promise for an efficient and fair remedy for those children who suffer vaccine-related injury and illness.

B. GOVERNMENTAL COMPENSATION SYSTEMS

In Manitoba, the general tort remedies are supplemented and, in some cases, replaced by governmental no-fault schemes. It will become apparent that few serve the needs of vaccine-damaged children, but they do provide precedential models of discrete no-fault schemes targeted at certain classes of persons suffering from accidental injury and disease.

The Workers' Compensation scheme provides workers, who are disabled as a consequence of workplace accidents or industrial disease, with guaranteed no-fault benefits. It is funded by levies on employers. Workers have no right to sue any employer or employee covered by the scheme. The Manitoba Personal Injury Protection Plan provides no-fault benefits to those who are injured in motor vehicle accidents. It is funded by a levy on the owners and operators of motor vehicles. No tort action is available for personal injuries arising from motor vehicle accidents. The Criminal Injuries Compensation scheme under *The Victims' Rights Act* provides no-fault compensation to the victims of criminal violence. The scheme is funded from general tax revenues. Tort actions against offenders, however, continue to be permitted. The benefits provided by these plans include future care costs, income replacement, payments for permanent disability and death benefits. The actual amounts are calculated in accordance with statutory formulae contained in the empowering legislation or regulations. Generally the benefits are lower than tort damages.

These three schemes clearly do not address vaccine injuries suffered by children. There are, however, other schemes that may assist in some cases. There is a wide range of social welfare programs including federal programs such as Employment Insurance, Canada Pension Plan and the federal contribution to health services insurance. The first two are employment related and are not relevant to vaccine injuries. Free health services are, of course, of crucial importance to those injured by vaccines. Additionally, there are some taxation provisions which allow deductions for the expenses of disabled persons. An ultimate safety net is provided by the provincial social allowance program. It is means-tested and covers all of those who are unable to support themselves as a consequence of misfortune.

C. PRIVATE PROTECTION

There is significant private sector involvement in the Manitoba accident compensation system. Private first party life and disability insurance on an individual or group basis is

---

[9] *Rothwell* v. *Raes*, *supra* n. 4, at 353.

increasingly common. These initiatives are, however, tailored primarily for adults and provide no coverage for childhood vaccine injuries.

The Manitoba accident compensation system is a sophisticated and humane response to the plight of those who suffer injury or illness as a consequence of accidental conduct. It is comprised of a fragmented congregation of compensatory vehicles which channel very large amounts of money to persons disabled by accidents. The current system does not, however, serve the victims of childhood vaccinations well. The prompt, efficient and fair compensation of those who suffer vaccine damage in childhood depends upon a further compensatory initiative targeted at them. The case for such a scheme is canvassed in the next Chapter.

CHAPTER 4

THE CASE FOR THE NO-FAULT COMPENSATION OF CHILDHOOD VACCINE INJURIES

A variety of factors make vaccine injuries unique and support the case for a special, targeted, no-fault compensation scheme to address the financial needs of the few random victims of Manitoba's system of routine childhood immunization. First, although vaccination is not compulsory, there is considerable governmental and social pressure to participate in the immunization process. The government promotes, encourages and facilitates the complete vaccination of all children in Manitoba. Parents are persuaded to place great reliance in the integrity and safety of the routine childhood immunization system and to expose their healthy children to it. Secondly, the province and its people benefit greatly from the immunization of its children. The process not only provides personal protection to the recipient from disease but also provides protection for the whole community by reducing the incidence of communicable disease. This results in a significant saving to government in reduced health care costs and to business by avoidance of a loss of productivity arising from the parental care of sick children. Childhood vaccination is, therefore, not merely a selfish act; it is an altruistic act to the advantage of the whole community. The extent of societal benefits that are secured suggests a degree of community responsibility for the random losses that are inflicted. Thirdly, the victims of childhood vaccination gave no *personal* consent to the process. In almost all cases, a substitute decision maker acted for the child. Of necessity, full reliance was placed on the decisions of others. Fourthly, as pointed out in the previous Chapter, the current accident compensation system in Manitoba is inadequate to the task of providing appropriate compensation to vaccine-injured children. Fifthly, vaccine-injured children are among the most vulnerable of Manitoba's citizens and they will often carry the consequences of their disability through the full course of their lifetime. Finally, an adequate system of compensation for vaccine injuries will support and strengthen the immunization system by reassuring parents that, in the rare instances where there are tragic consequences, they are not alone but will receive the financial support of government.

The factors supporting a targeted compensatory vehicle in respect of childhood vaccine injuries must be balanced against some which dictate caution. First, it may be argued that such a scheme would differentiate unfairly between those who suffer a childhood vaccine accident and those who suffer some other kind of medical accident. The former would receive guaranteed benefits and the latter would have to rely on the tort system with uneven results. The distinction may, however, be justified on the grounds that the former participate in a public health campaign at a vulnerable age and receive treatment unrelated to any personal current illness. It is also a fact that the current accident compensation system in Manitoba is replete with inconsistency in its treatment of accident victims. It is not clear why, for example, the victims of automobile accidents deserve better treatment than the victims of vaccine accidents. Secondly, the establishment of a compensation plan for victims of vaccine accidents may undermine the public

confidence in an important public health initiative and may lead to a lowering of vaccination rates to the general disadvantage of the public. However, it is unlikely that any governmental initiative which depends on public support and confidence will prosper by unduly discounting risks and disadvantages. An open recognition and communication of all the material risks and the anticipated benefits of vaccinations coupled with an appropriate vehicle to compensate those few who may suffer loss is a better recipe for the integrity and ultimate success of the immunization program. Thirdly, even if the right to sue in tort is retained, the development of a supplementary no-fault plan may diminish the power of tort law to influence positively the conduct of health care professionals and manufacturers. The conventional wisdom is that the threat of tort liability acts as a deterrent to faulty and wrongful conduct. At the least, a no-fault scheme will further diminish reliance on the tort system with a potential loss of deterrence and a correlative increase in risky conduct. In theory, this may be correct but the experience of health care professionals and manufacturers in relation to vaccine injuries is one in which there is no reported Canadian case where anyone has been held liable. The loss of deterrence in those circumstances is unlikely to be great. Finally, it has been suggested that a no-fault scheme may lead to a public perception that vaccines are dangerous when medical evidence remains inconclusive, when newer vaccines are possibly less risky than those previously used and when future vaccines are likely to be safer than those currently used. It may, therefore, entrench an attitude to vaccines which is unsubstantiated and unwarranted and may lead to lower immunization rates. This perception may, however, be countered by the fact that, judging by the experience of other jurisdictions, there will not be a large number of successful claimants.

On balance, the Commission accepts the case for a special compensatory mechanism for the victims of childhood vaccine accidents. Vaccine injury compensation plans are a well established and important component of the immunization programs of many western jurisdictions. With the exception of Québec, Canada has failed to provide a compensatory safety net for the random victims of its immunization program. We recommend that this be remedied in Manitoba and we turn to the experience of some of those jurisdictions with vaccine injury compensation plans to identify the issues involved and possible solutions.

CHAPTER 5

VACCINE COMPENSATION SCHEMES IN OTHER JURISDICTIONS

Many jurisdictions throughout the world have introduced special compensatory initiatives to address vaccine-related injury and illness. Those jurisdictions include: Germany (1961), France (1964), Japan (1970), Switzerland (1970), Denmark (1972), New Zealand (1974), Sweden (1978), United Kingdom (1979), Québec (1987), United States (1988), Taiwan (1988), Italy (1992) and Norway (1995). Detailed information was not readily available on the operation of all these schemes. Consequently, consideration is given to only four of them: Québec (the only province in Canada to have such a scheme), the United States, and the two other common law jurisdictions with compensatory schemes, the United Kingdom and New Zealand. We also include a Chart in Appendix D[1] which gives general comparative information on all the schemes worldwide. A description of the designated schemes will raise the issues that must be addressed in formulating a compensation plan of this nature.

A. QUÉBEC

1. Introduction

The Québec no-fault vaccine injury compensation plan was prompted by the unsuccessful litigation of Nathalie Lapierre. One week after being vaccinated for measles, Nathalie suffered acute viral encephalitis which left her in a state of permanent and almost total disability. An action was brought against the government of Québec which in turn joined the manufacturer and the distributor of the vaccine. The trial judge found a causal link between the vaccine and Nathalie's disability but found that none of the defendants was negligent. Nevertheless, the judge found the *government* strictly liable for the disability.[2] The strict liability of the government was based on an innovative interpretation of a provision of the Québec *Civil Code*. This decision was, however, reversed on appeal by the Québec Court of Appeal.[3] The matter proceeded to the Supreme Court of Canada[4] which heard a variety of imaginative and innovative arguments in support of the trial judge's opinion in favour of the strict liability of government for the adverse

---

[1]The chart is reproduced from G. Evans, "Vaccine Injury Compensation Programs Worldwide" (1999), 17 Vaccine S25- S35. Some useful information on worldwide compensation plans, including the four schemes considered in this Chapter, was provided in the papers and presentations given at the International Workshop on Vaccine Injury Compensation Plans held in Washington, D.C., May 16-18, 2000.

[2]*Lapierre* v. *Procureur Général de la Province de Québec* (1979), 13 C.C.L.T. 1.

[3]*Procureur Général de la Province de Québec* v. *Lapierre* (1983), 27 C.C.L.T. 190.

[4]*Lapierre* v. *Attorney-General of Québec* (1985), 16 D.L.R. (4th) 554.

consequences of vaccination programs funded and supported by it. None of those arguments was successful. No liability was imposed. The message of this litigation was clear. Proof of *negligence* is as essential a component of tort liability in Québec as it is in the common law provinces and there is little likelihood of negligence and causation being established against government, vaccine manufacturers or health care professionals for vaccine injuries.

The state of Québec law after *Lapierre* reflected that of Ontario after *Rothwell*. Unlike Ontario, the Québec government introduced a no-fault plan.

2. The Compensation Plan

In 1985, the Québec government introduced an amendment to the *Public Health Protection Act* entitled *Division III.1 Indemnities for Victims of Immunizations*.[5] The plan provides compensation to *any person* (adult or child) for adverse reactions that are causally linked to a vaccine. If causation is proved and the claimant meets other necessary criteria, compensation is paid in accordance with the benefits outlined in the *Automobile Insurance Act*.[6] That Act creates a no-fault plan for the victims of automobile accidents similar to the Manitoba Personal Injury Protection Plan under Autopac.

3. Vaccines Covered

All vaccinations in Québec are voluntary. Adverse reactions to the following vaccinations are covered by the plan: diphtheria, whooping cough, tetanus, poliomyelitis, measles, rubella, mumps, tuberculosis, viral hepatitis A and B, influenza, rabies, botulism, typhoid, cholera, plague, yellow fever, meningococcus infections, pneumonic infections, haemolysis due to anti-Rh iso-immunization, poisoning due to a bite from a venomous snake, haemophilus influenzae infections, humoral immune deficits, staphylococci infections, gaseous gangrene, chicken pox and smallpox.[7] This list is intended to cover all vaccines given in the province.

4. Compensable Injuries

Compensation is paid to any person of any age who suffers *grave and permanent mental or physical damage* caused by a vaccination or by a disease contracted from an immunized person or as a result of being a foetus of an immunized person. Where a vaccination causes death,

---

[5] *Public Health Protection Act*, R.S.Q. c. P-35.

[6] *Automobile Insurance Act*, R.S.Q., c. A-25.

[7] *Regulation respecting the Application of the Public Health Protection Act*, R.S.Q., c. P-35, r.1, s. 233.

compensation is paid to those family members who would be entitled to death benefits under the automobile insurance plan. The claimant must establish a causal link between the vaccine and the disability or death on the balance of probabilities.

5. Compensation

As noted earlier, the quantum of compensation is calculated in accordance with the scheduled benefits under the Québec no-fault automobile insurance plan. The Manitoba Personal Injury Protection Plan is closely modelled on the Québec scheme. The kinds of benefits payable include income replacement, compensation for physical disability, future care costs, rehabilitation expenses and death benefits to family members. There are clear administrative and cost advantages in tying compensation to an existing compensatory mechanism so long as the quantum is reasonable and fair to the claimant. A table detailing the various indemnities available to a claimant in Québec is set out in Appendix E.

6. Procedures

The claimant must make a written application to a three member medical assessment committee in the Department of Health and Social Services, hereafter referred to as the "Committee".[8] The Committee is comprised of a physician nominated by the Minister of Health and Social Services, a physician nominated by the claimant and a third physician nominated by the other two members. The claimant must institute a claim by making a written signed declaration indicating *inter alia:*

- the name, date of birth, social security number and address of the victim;
- the name, address, and capacity of a person who is acting as a representative of the victim;
- the name and nature of the vaccine administered, the place where it was given, the name of the person who gave it and the date of the vaccination;
- the date when the symptoms first manifested themselves or the date of death.

The claimant must attach to this declaration a medical certificate setting out the disability suffered by the claimant and attesting to the causal link with the vaccination. Information must also be given to permit the calculation of benefits under the automobile insurance plan.

The claimant's file is then reviewed by the Committee. The Committee has a number of functions. First, it must review the file and evaluate the damage suffered. Secondly, it evaluates a probable causal link between the damage suffered and the vaccination. Consideration is given

---

[8]The procedures are set out in the regulations: *Regulation respecting the Application of the Public Health Protection Act*, R.S.Q., c. P-35, r.1, ss. 234ff.

to the reality, nature and severity of the illness or injury, the mechanism which produced the injury, the delay between the vaccination and the onset of symptoms, the evolutionary continuity of the disability, the correlation between any prior illness and the after-effects and the prior health of the individual. The standard of proof is the balance of probabilities. The Committee must request the opinion of a specialist in immunology when one of the members of the Committee feels that such an opinion is necessary to establish the probability of a causal link. Thirdly, it calculates the amount of the indemnity or compensation to be paid in accordance with the schedule of benefits under the automobile insurance plan. Fourthly, it makes recommendations to the Minister of Health and Social Services.

In the discharge of its functions, the Committee must examine the claimant or have another physician do so. This includes both the taking of a medical history and a physical examination. This will assist in the making of a diagnosis and in the assessment of the degree of permanent incapacity suffered by the claimant necessary to calculate the benefits under the automobile insurance plan. The regulations also make provision for the claimant to be heard. The Committee's decision is by majority and reasons must be provided. The decision is forwarded to the Minister of Health and Social Services who has the final decision on whether or not compensation will be paid and the amount of it. The Minister has an arrangement under which the automobile insurance plan actually pays the indemnities in cases decided in favour of the claimant.

7. Appeals

The decision of the Minister of Health and Social Services may be appealed both on the merits of the decision and as to the quantum of compensation to the *Commission des Affaires Sociales*. The *Commission* is a review body which has jurisdiction to hear appeals and applications under social welfare legislation. It deals with matters such as social aid and allowances, mental health protection, health and social services and pension plans. Its decisions are binding and final. The President and members of the *Commission* are lawyers. The Health and Social Services Division of the *Commission* hears appeals in respect of vaccine compensation claims. The quorum for a hearing is three members including one member who is a physician. An appeal is initiated by a written declaration filed within 90 days of the decision appealed from. A copy of the declaration is given to the respondent, the Minister of Health and Social Services. Each party has a right to be heard and evidence may be introduced. Representation by counsel is permitted. The decision of the *Commission* must be given in writing and with reasons. There is no further appeal. The decision may, however, be registered in the Superior Court on a motion by the *Commission* or an interested party and thereafter it has the same force and effect as a judgment of that court. The records concerning the appeal are confidential. Decisions are published without names.

8. Funding

The funding for the plan comes from the consolidated revenue fund of the Province of Québec.

9. Limitations

Claims must be brought within three years of the date of the vaccination or, in the case of death, three years from the death. In the case of latent damage, the claim must be made within three years of the damage becoming apparent.

10. Tort Claims

The no-fault plan does not abrogate any tort claim that may be available to the claimant. In the event of the recovery of tort damages, there must be reimbursement of any indemnities received under the no-fault plan and, if the claimant does not pursue a tort claim, the Minister of Health and Social Services has a subrogated right to pursue the tortfeasor and recoup any indemnities paid or payable to the claimant. Any additional moneys recovered would, presumably, belong to the claimant.

11. Retroactive Claims

The scheme covers claims arising before the date of implementation of the scheme. Any claim which arose before December 18, 1987 is considered to have arisen on that date for the purpose of the limitation period.

12. Claims Experience

There have been 117 claims under the Québec scheme. Of these claims, 20 have been compensated. The low number probably reflects the difficulty of establishing causation. Just over 2.7 million dollars has been paid in benefits. The average amount paid per person is $135,000. Over half of the awards have gone to the victims of the OPV (oral polio vaccine) which is no longer used in Manitoba.

13. Miscellaneous

The *Public Health Protection Act* is currently under review but no significant change is anticipated for the vaccine injury compensation plan.

B. UNITED STATES

1. Introduction

In 1986, the Congress of the United States enacted the *National Childhood Vaccine Injury Act*[9] which established a federal no-fault compensation scheme for injuries arising from vaccines routinely given to children. This initiative was prompted by two developments. First, in the United States in the early 1980s there was a judicial trend away from the traditional fault-based liability of the manufacturers of vaccines to a strict liability for vaccine-related injuries. This created a great deal of alarm in the industry. The price of vaccines rose substantially in anticipation of much greater tort liability costs and some manufacturers began to withdraw from the field. There was, therefore, a real concern about the long term viability of the system of routine childhood immunization. Secondly, simple justice suggested that those who suffer the adverse consequences of a vaccination program designed for the public benefit should not bear the loss alone. This argument was strengthened in the United States by the fact that the vaccination program is mandatory. All states require the vaccination of children before entry to school.

The National Vaccine Injury Compensation Program, therefore, sought to accommodate a number of interests: the interests of manufacturers in being free from burdensome tort liabilities that threatened the commercial viability of their business; the interests of the public in maintaining a strong and effective childhood immunization program; and the interests of vaccine-injured children in securing compensation in a timely and inexpensive manner. [10]

2. The Compensation Program

The Vaccine Injury Compensation Program is a federal no-fault plan which is designed to provide compensation for injuries arising from vaccines routinely given to children. It is administered jointly by the Department of Health and Human Services, the United States Court of Federal Claims and the Justice Department.

---

[9] 42 U.S.C.A. §§300aa-1 to -34.

[10] Much of the information on the National Vaccine Injury Compensation Program is drawn from E.W. Kitch, G. Evans and R. Gopin, "U.S. Law" in S.A. Plotkin and W.A. Orenstein, eds., *Vaccines* (3rd ed., 1999) 1165-86; Health Resources and Services Administration, Bureau of Health Professionals, National Vaccine Injury Compensation Program, http://www.hrsa.dhhs.gov/bhpr/vicp/; U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Vaccine Adverse Events Reporting System (VAERS), http://www.fda.gov/cber/vaers/vaers.htm; and CDC National Immunization Information Program, http://www.cdc.gov/nip.

3. Vaccines Covered

The program covers those vaccines which are routinely administered to children. These include the Diphtheria, Tetanus and Pertussis (DTP, DtaP [accellular pertussis], DTP-Hib, DT, Td, and TT [tetanus toxoid]), mumps, measles and rubella (MMR, MR, M, R,), polio (inactivated polio vaccine [IPV] and OPV), hepatitis B (HBV), haemophilus influenza type B(Hib) and varicella-zoster virus (VZV) vaccines. Rotavirus (RV) vaccine was added on October 22, 1998. Its use, however, has been discontinued because of reports of serious intestinal blockages in some babies. Eight years of retroactive coverage is provided for vaccine-related adverse events associated with new vaccines added to the list. Vaccines for children recommended in the future by the Center for Disease Control and Prevention are automatically added to the list of designated vaccines. Congress must, however, set the appropriate excise tax on any new vaccine recommended by the Center for Disease Control and Prevention before they are covered by the program.

4. Compensable Injuries

The Vaccine Injury Compensation Program covers all death, injury and illness arising from any one of the routine childhood vaccinations listed earlier. The effects of any injury must have continued for at least six months and, until very recently, at least $1000 in non-reimbursable medical costs must have been incurred.[11] These kinds of requirements operate to exclude minor and frivolous claims. The perennial difficulties in establishing a causal link between the vaccine and the injury suffered are alleviated to some extent by the use of a *Table of Injuries* and the *Qualifications and Aids to Interpretation* (a copy of the *Table* and *Aids* dated October 22, 1998 is attached as Appendix F). There is a presumption of causation if an injury listed in the Table occurs within a prescribed time following the giving of the vaccine. For example, if anaphalaxis occurs within four hours of the administration of the DPT vaccine, there is a presumption that the vaccine caused it. In essence, a temporal association between a vaccine and a Tabled injury is sufficient to create a presumption of causation. The government may attempt to rebut this presumption by presenting evidence of a definitive alternative cause such as an infection or trauma. It cannot, however, be rebutted by "any idiopathic, unexplained, unknown, hypothetical or undocumentable injury, illness or condition."[12] If the claimant's injury is not found in the Table of those presumptively connected with the vaccine, or it did not arise within the prescribed time period, he or she may independently of the Table prove that the injury is vaccine related. In these cases, the claimant must prove "a logical sequence of cause and effect supported by a

---

[11]This requirement was removed on October 21, 1998 (Public Law 105-277, 112 Stat. 28681-348). The change insures that individuals such as medicaid recipients and others not able to meet the threshold are no longer penalized.

[12]42 U.S.C.A. §§300aa-13(a) (2).

reputable medical or scientific explanation that the vaccine was the reason for the injury."[13] A claimant who establishes that a vaccine significantly aggravated a pre-existing condition is also covered by the plan. Understandably the Vaccine Injury Table is subject to periodic change as new scientific evidence finds new risks and side effects or suggests that side effects which were initially attributed to a vaccine are unrelated to it. For example, on March 10, 1995, the Department of Health and Human Services added chronic arthritis to the Table as being associated with the rubella vaccine. Conversely, in a decision severely criticized by some, residual seizure disorder and hypotonic-hyporesponsive (shock collapse) episode were removed as Table injuries in respect of DTP. On March 24, 1997, brachial neuritis was added as a risk of tetanus and encephalopathy was removed as an injury associated with that vaccine. Other changes were also made in respect of the measles-containing vaccines and the live polio virus vaccine.

5. Compensation

The amount of compensation payable to a claimant is assessed on tort principles. Compensation for future care costs and loss of income is normally made in the form of an initial lump sum and an annuity that will provide a stream of income during the life of the claimant. There are, however, certain limits and qualifications in respect to other heads of damage. Claims for pain and suffering are limited to $250,000 and there is no claim on the part of family members for loss of companionship of the injured claimant. Punitive damages are not awarded. Compensation for fatality claims is limited to $250,000. Reasonable attorney fees are recoverable whether or not the claimant is successful. The average award made to claimants is found in the National Vaccine Injury Compensation Program Monthly Statistics Report through June 7, 2000 found in Appendix G.

6. Procedures

The procedures for bringing a claim under the National Vaccine Injury Compensation Program are modelled on the civil litigation process. Petitions are filed in the Court of Federal Claims against the Secretary of the Department of Health and Human Services as nominal defendant. Extensive medical and hospital records must be provided by the petitioner. An initial review and investigation process is conducted within 90 days by the medical staff of the Vaccine Injury Compensation Program. This culminates in a recommendation to accept or decline the claim. The recommendation is forwarded to a Special Master of the Court by the Department of Justice attorney representing the Department of Health and Human Services. Recommendations to accept claims are almost always ratified by the court and the need for a hearing is avoided. In other cases, a hearing is held before the Special Master. Most hearings take no more than two days. Approximately 50% of the claims rejected by the Vaccine Compensation Injury

---

[13] *Grant* v. *Secretary HHS* 956 F.2d 1144 Fed. Cir.1992 cited in *Vaccines*, *supra* n.10, at 1174.

Compensation Program physicians are allowed after a hearing. After eligibility is established, compensation on tort principles must be calculated. This is normally achieved by a process of negotiation between the parties. This process is time consuming and is a significant factor as to why the average time between claim and disposition is 2.5 years.

7. Appeals

Appeals against the decision of a Special Master may be brought before a judge of the Court of Federal Claims. Further appeal is to the Federal Circuit Court of Appeals and then to the Supreme Court.

8. Funding

The Vaccine Injury Compensation Program is funded from an excise tax paid by the manufacturer on the sale of every dose of childhood vaccine. The tax is accumulated in the Vaccine Injury Compensation Fund. Initially the tax varied in relation to the degree of risk created by the particular vaccine. On August 5, 1997, this risk-based excise tax was replaced with a flat rate of 75¢ per dose of vaccine. Consequently, a three dose vaccine such as DTP carries a $2.25 tax.

9. Limitations

A claim for a vaccine injury must be made within 36 months of the appearance of the claimant's first symptoms.

Fatality claims must be made within 24 months of the death and within 48 months of the onset of the vaccine-related injuries from which death has occurred.

10. Tort Claims

The action in tort for damages is severely limited by the Vaccine Injury Compensation Program. The protection of vaccine manufacturers against the uncertainties and burdens of the tort system was one of the motivating factors of the plan. No tort litigation may be commenced against a manufacturer or a health care provider in respect of a vaccine injury until a claim has been pursued through the Vaccine Injury Compensation Program and the claimant has either refused the offered compensation or has failed to establish his or her case. Furthermore, a plaintiff may not allege against a manufacturer that the vaccine has a design flaw or that there has been a failure to warn of the inherent risks of the vaccine. Moreover no punitive damages are available unless gross negligence is established. Consequently, there are very few law suits against

manufacturers or health care providers.

11. Retroactive Claims

The Vaccine Injury Compensation Program also made provision for the coverage of vaccine injuries that arose before the start-up date of the Program (October 1, 1988). The treatment of these claims is somewhat different from the claims arising after that date. A deadline of January 31, 1991 was set for the filing of these claims.[14] Until that date, these claimants were given the option of pursuing their tort remedies or filing under the Program. Compensation awarded under the plan is funded by an annual Congressional appropriation. Compensation is available for unreimbursable vaccine-related medical costs. Attorneys' fees, pain and suffering and lost wages are subject to a $30,000 combined cap. Almost all of the pre-1988 claims have either been fully adjudicated or are in the adjudicative process. There is also provision for retroactive claims in respect of new vaccines added to the Vaccine Injury Compensation Program. The coverage which reaches back eight years is subject to a two year filing period running from the time the vaccine is added to the Program.

12. Claims Experience

The claims experience is found in the National Vaccine Injury Compensation Program Monthly Statistics Report (June 7, 2000, see Appendix G). In 1999, for example, 5 pre-1988 claimant petitions were filed and 406 post-1988 claimant petitions were filed. In 1999, 90 awards were paid for post-1988 claimants. The average award in 1999 for post-1988 claims was $1,433,319. Awards have ranged up to $8 million. Of the 5,385 petitions filed by April 5, 1999, 71.7% dealt with the DTP/P/DTP-HIP vaccines; 14.5% MMR or components; 10% IPV or OPV; 1.9% Tetanus/Td/DT; 0.5% new vaccines; and 1.5% other.

13. Miscellaneous

The Vaccine Adverse Events Reporting System (VAERS), operated by the Food and Drug Administration and the Center for Disease Control, monitors the immunization system for vaccine-related injury and illness. Recently, for example, the use of the Rotavirus vaccine was indefinitely suspended after reports of bowel obstructions developing in infants within weeks of the vaccine being given. A VAERS reporting form must be completed in respect of:

- any event set forth in the Vaccine Injury Table that occurs within the prescribed time period or within 7 days if that is longer;

---

[14]This deadline does not, however, appear to have been strictly enforced.

- a contra-indicating event listed in the manufacturer's insert.

The VAERS system also receives other reports of real or suspected adverse results of vaccines from interested parties.

C. UNITED KINGDOM

1. Introduction

In 1979, the *Vaccine Damage Payments Act*[15] was passed in the United Kingdom primarily to provide compensation for vaccine-injured children. The legislation resulted from significant public concern about vaccine injuries. There was particular alarm about the side effects of the whole cell pertussis vaccine. Declining vaccination rates associated with the anxiety over that vaccine and indications from the Royal Commission on Civil Liability and Compensation for Personal Injury that it was about to recommend some kind of financial assistance for those seriously injured from vaccines recommended by the public health authorities prompted the government to act.

2. The Compensation Program

No discrete administrative body was set up to deal with vaccine injury claims. The program created by the *Vaccine Damage Payments Act* is run through the Department of Health and Social Security and final decision making is given to the Secretary of State for Social Security.

3. Vaccines Covered

The *Vaccine Damage Payments Act* lists the vaccines that are covered by the compensation plan. The intention is to cover all vaccines routinely administered to children. Vaccines against the following listed diseases are covered: diphtheria, tetanus, whooping cough, poliomyelitis, measles, rubella, tuberculosis, smallpox, mumps, haemophilus influenza type B (Hib) and any other disease specified by the Secretary of State for the purposes of the Act.

4. Compensable Injuries

Compensation is payable to those claimants who are seriously disabled or were seriously

---

[15] *Vaccine Damage Payments Act 1979* (U.K.), 1979, c. 17.

disabled before death as a consequence of a vaccination against a listed disease. Severe disability is defined as at least an 80% disability. Coverage is also given to anyone who is severely disabled as a consequence of a vaccine administered to the mother while she was pregnant or as a consequence of being in contact with someone else who had been vaccinated against a designated disease. The claimant must have been vaccinated in the United Kingdom after July 5, 1948 and must, except in the case of vaccinations for rubella or poliomyelitis, have been vaccinated before the age of 18.

5. Compensation

A lump sum payment of £40,000 is paid to each successful applicant. No provision is made for an individualized assessment of personal losses.

6. Procedures

A claim is made to the Vaccine Damage Payments Unit of the Department of Health and Social Security. It is evaluated by a medical officer who determines if the injury was caused by the vaccine. This is resolved on the balance of probabilities. A recommendation is made to the Secretary of State who makes the final decision. If it is decided that a payment will not be made, a notice giving grounds for the disallowance is given to the claimant. If the grounds of disallowance are that the claimant did not suffer a serious disability caused by the vaccine, an application for review may be made and the matter is referred to an independent medical tribunal, known as the Vaccine Damage Tribunal.

7. Appeals

Section 5 of the *Vaccine Damage Payments Act* allows the Secretary of State to reconsider a determination made on his behalf where there has been a change in circumstances since the original decision or where the decision of the Vaccine Damage Tribunal was based on a lack of knowledge or error at the time of its decision.

8. Funding

Payments are made from general taxation revenue.

9. Limitations

The claim must be brought within six years beginning on the latest of the following dates:

the date of the vaccination to which the claim relates, the date on which the disabled person attained the age of two and May 9, 1978.

10. Tort Claims

The Act does not foreclose the claimant's tort rights in any way.

11. Retroactive Claims

Claims for serious disability arising from vaccines administered after July 5, 1948 are accepted. The families of children who died as a consequence of a vaccine before the operation of the Act are not covered.

12. Claims Experience

Between 1979 and March 2000, 4217 claims were filed. Compensation was paid to 896 claimants.[16]

13. Miscellaneous

On June 27, 2000, the British government announced that it intended to introduce legislation increasing the payment threshold from £40,000 to £100,000, dropping the six year time limit for claims, permitting anyone up to the age of 21 to ask for compensation and reducing the severity of disability from 80% to 60%.[17]

D. NEW ZEALAND

1. Introduction

There has been no independent initiative in New Zealand to address vaccine injuries. Prior to 1974, these injuries were controlled by the tort system. Since that time, vaccine injuries have been covered under the New Zealand Accident Compensation Scheme (ACC). The Accident

---

[16]Department of Social Security, London, England, "Vaccine Damage Payments Scheme - United Kingdom" (April 18, 2000), paper prepared for the International Workshop on Vaccine Injury Compensation Programs held in Washington, D.C., May 16-18, 2000.

[17]http://abcnews.go.com/wire/World/reuters20000627_2395.html

Compensation Corporation is a statutory corporation which provides universal 24 hour per day no-fault compensation in respect of personal injury and death caused by accident.

2. The Compensation Program

The Accident Compensation Plan currently operates under the *Accident Insurance Act* 1998. Whether or not a vaccine injury is covered by the scheme and the benefits available depends on the provisions of that legislation.

3. Vaccines Covered

There are no restrictions under the *Accident Insurance Act* on either the kind of vaccine causing personal injury or death or on the age of the claimant.

4. Compensable Injuries

The Accident Compensation Scheme covers all personal injury and death caused by an *accident*. Consequently, the term "accident" is pivotal to the scope and coverage under the scheme. This concept, however, proved difficult to apply to injuries arising from medical treatment. This prompted the Legislature to adopt the term medical misadventure to define compensable events in the field of medical treatment. Medical misadventure is carefully defined in sections 34-37 of the *Accident Insurance Act*. Medical misadventure is defined as either *medical error* or *medical mishap*.

Medical error is found where the injury is caused by a failure of a health care professional to exercise reasonable care and skill. There is no medical error merely because the desired results of medical treatment are not achieved or because different medical decisions or treatments may have achieved better results for the patient. A departure from standard medical practice similar to negligence under the Canadian tort system is required. Medical error may occur in the administration of vaccines. The vaccine may be prepared or stored incorrectly, contra-indications may be ignored, sterilization protocols may not be followed and vaccinations may be given at the wrong site. In these situations, the claimant's injuries arise from medical error and the claimant is compensated for losses arising from this category of medical misadventure.

A vaccine injury may alternatively amount to a *medical mishap*. Medical mishap arises when there are adverse consequences of medical treatment given by a registered health care professional. The adverse consequence must, however, be *severe* and *rare*. The consequence is severe if it results in death or necessitates hospitalization for more than 14 days or results in a significant disability lasting more than 28 days in total. It is rare if it arises in fewer than 1% of cases in which that treatment is given. There is unlikely to be difficulty in establishing that a

vaccine injury is rare. Greater difficulty is encountered in establishing the requirement of severity.

In cases of vaccine injuries, the most common point of contention is causation. Causation is decided on the balance of probabilities. Each case is handled individually and reliance is placed on the medical evidence and the assistance of expert consultants. There is no institutionalized use of Tables similar to that used under the American National Childhood Vaccine Injury Compensation Program.

5. Compensation

The compensation available to those with vaccine injuries is determined by the normal assessment rules and procedures under the *Accident Insurance Act*. Statutory benefits include necessary future care costs including medical and pharmaceutical expenses, attendant care, home help, aids, appliances and equipment, transportation costs and rehabilitation expenses. The claimant is also eligible, at age 18, to earnings-related compensation if the injury results in a partial or total incapacity to work. In cases of vaccine injury where the claimant has never been an earner, "deemed earnings" provisions are used to calculate the claimant's potential earnings. A very small allowance known as an Independence Allowance is available to compensate the claimant's non-pecuniary loss such as permanent physical or mental disability. The weekly payment is calculated with reference to the claimant's degree of permanent disability. In 1998, the maximum payment for those with an incapacity in excess of 80% was $61.68 per week.

6. Procedures

Claimants and their physicians complete the appropriate standard claims form which is then sent to the nearest Accident Compensation Corporation Registration Centre. All medical claims (including vaccine injuries) are forwarded to the Medical Misadventure Unit in Wellington which determines if the injury arises from medical misadventure and is, therefore, covered by the scheme. Contentious claims prompt investigation by clinical advisors including the securing of medical and consultants' reports. Each claim is then assessed by an independent medical advisor who recommends the claim be accepted or rejected. Claims may then be accepted, declined or, in complex cases, be placed before the Medical Misadventure Advisory Committee. The Committee makes a preliminary recommendation to the Corporation. Both the claimant and the Corporation have 15 days to comment on this preliminary recommendation. The Committee may meet again to reconsider the claim in the light of new information. Final advice is then given to the Corporation on coverage.

7. Appeals

A disappointed claimant may request a Review Hearing by an independent Review

Officer. Further appeals may be taken first to the District Court and then, on a matter of law only, to the High Court.

8. Funding

The Accident Compensation Scheme is funded from a wide range of sources including levies on employers, employees, the owners of motor vehicles, government and earnings on investments. Neither health care professionals nor manufacturers pay any levy in that capacity alone.

9. Limitations

Generally, claims must be made within one year of the person suffering the injury but late claims are not rejected unless the delay prejudices the Corporation in its ability to make decisions.

10. Tort Claims

No tort claim is available for an injury or death that is accepted by the Accident Compensation Corporation as arising from a medical misadventure. If coverage under the Act is denied, a tort claim may be available.

11. Retroactive Claims

No provision was made for any retroactive claims when the Accident Compensation Scheme was introduced in 1974.

12. Claims Experience

From July 1, 1992 to April 25, 2000, 293 vaccination claims were filed. Of these 77 have been accepted.[18]

---

[18]R. Matthews, "Vaccination Compensation in New Zealand", paper presented at the International Workshop on Vaccine Injury Compensation Programs held in Washington, D.C., May 16-18, 2000.

CHAPTER 6

RECOMMENDATIONS FOR A MANITOBA CHILDHOOD VACCINATION INJURY COMPENSATION PLAN

A. INTRODUCTION

Earlier in this Report, the case was made for a discrete statutory compensation plan for injury and illness caused by childhood vaccination. The experience of four jurisdictions has been reviewed to isolate the issues that must be addressed and to identify ways in which these issues might be resolved. These matters are addressed in this Chapter. The individual recommendations on each of these issues are made with reference to six guiding general principles. First, compensation must be provided on a no-fault basis. Secondly, compensation of vaccine-damaged children is a community responsibility. It is a price to be paid for the public benefits derived from the immunization system. Thirdly, compensation must be fair and adequate but not lavish. Fourthly, the procedures for making a claim should be as informal and inexpensive as is possible given the difficulty of some of the decisions that will arise. Fifthly, advantage should be taken of existing institutions and procedures to the extent possible to enhance economy and efficiency. Sixthly, overall administrative costs should be minimized to the extent possible. Against this background, we examine the various issues that must be addressed in the proposed *Childhood Vaccination Injury Compensation Act*.

B. THE COMPENSATION PLAN

The framework of the plan and the rights of claimants should be set out as clearly as possible in an independent statute of the Manitoba Legislature. Special attention should be given to the clarity and the accessibility of the statutory language to facilitate a clear understanding of the plan by the public. The use of regulations should be minimized because of their lesser accessibility and because of the potential public confusion when more than one document defines the scope of entitlement programs. A title such as *The Childhood Vaccination Injury Compensation Act* would clearly and directly identify the substance and purpose of the legislation.

RECOMMENDATION 1

That a statute entitled* The Childhood Vaccination Injury Compensation Act *be enacted in Manitoba establishing a compensation plan for vaccine-damaged children.

C. VACCINES COVERED

At a minimum, the plan should cover all children (persons under the age of 18) resident in Manitoba who receive routine vaccinations in Manitoba from a registered health care professional. There are, however, situations where children receive vaccinations that are not part of the routine vaccination program. Other vaccinations may be given for a variety of reasons including the health of the child or because the child will be visiting a foreign country that is subject to serious preventable diseases not normally found in Canada. In these situations, the vaccinations may be more for the personal health of the child and less for the public benefit to the community than those routinely sponsored and given to all children. Nevertheless, it is difficult to justify exclusions in these cases, particularly where there may be some marginal public benefit. It would be administratively advantageous and expedient to cover all children resident in Manitoba in respect of any vaccination given in Manitoba by a registered health care professional. It may be argued that protection be extended to all persons both adults and children who are vaccinated. Vaccination at any age may bring some public benefits by, for example, reducing the number of infectious people in the community. Flu vaccinations fall into this category. On the other hand, adults can be excluded justifiably on the basis that each adult determines personally the health care he or she desires and the risks he or she is willing to encounter. Moreover, adults are generally not receiving vaccinations at as vulnerable a moment in life as early infancy.

The Commission gave careful consideration to this issue. In its view, it is appropriate to give priority to vaccine-damaged children. Their age, vulnerability, dependence on substitute decision makers and the importance of the childhood immunization program justify preferential treatment. Nevertheless, the importance of immunization in the adult community is established and is likely to grow as more "adult" vaccines are introduced. The Commission recognizes the cogency of the argument to include adults within the plan. The Commission favours an incremental approach beginning with a plan that covers children and extending that plan to adults when experience suggests that to be a financially prudent and viable course of action. It should be noted that there is nothing in the recommended plan that would not permit an easy extension to cover the whole community.

RECOMMENDATION 2

That coverage be given to all persons who are vaccinated under the age of 18 provided that the vaccination was administered in Manitoba by a registered health care professional and the child was a resident in Manitoba at the time of the vaccination.

RECOMMENDATION 3

That, within a reasonable time after the implementation of* The Childhood Vaccination Injury Compensation Act, *the government give consideration to the extension of the plan to cover all vaccine recipients.

D. COMPENSABLE INJURIES

There are a number of ways of determining the compensable injuries. First, injury is used in a loose sense. Compensable injury includes not only trauma as a consequence of a vaccination but also any illness or death that arises from it.

Secondly, not all vaccine injuries can be compensated without inviting large numbers of trivial claims for minor and temporary adverse events. Administrative concerns, financial constraints and fairness suggest that a compensation scheme should target the most serious cases of vaccine damage. All schemes address this issue in some manner either by a description (e.g. grave and permanent disability, serious disability, long term disability), degree of permanent disability (e.g. 80% of total capacity) or by setting minimum medical costs or days of hospitalization (e.g. $1,000 medical expenses or seven days of hospitalization). All of these options have some disadvantages. Descriptive terms give rise to issues of interpretation and application. Assessing degrees of disability leads to difficult medical decisions. Reference to medical costs or the number of days of hospitalization necessitated by the injury fail to address the seriousness of the disability directly. There is much to be said for a description similar to that used in Québec (grave and permanent mental or physical damage). This clearly excludes minor and trivial claims and directly targets the most serious disabilities.

Thirdly, the perennial problem of causation must be addressed. The traditional civil burden of proof is that of the balance of probabilities. The burden normally falls on the claimant. This burden of proof has been found to be a very heavy one both in the tort process (the *Rothwell* case) and in some no-fault plans (Québec). The retention of the usual civil burden of proof may rule out deserving cases but the undue relaxation of causation principles risks the converse consequence of including undeserving cases. It is, however, probably better policy to err on the side of inclusion rather than exclusion particularly in an area of such inexactitude of medical and scientific evidence. A number of possibilities present themselves. Use may be made of a Table of Injuries similar to that used in the United States under their National Childhood Vaccine Injury Compensation Program linking temporally related adverse consequences with various vaccines. The development and continual update of a "made in Manitoba" Table may be beyond the financial and medical resources of the province. The United States' Table could be adopted by reference but that may create undue reliance on a foreign initiative, some criteria of which have been the subject of criticism. Alternatively, causation may be established where it is proved that a child was in good health before the vaccination and suffers some injury or illness within a set period such as a week after the vaccination. The risk of such a presumption is that it captures temporally related conditions which may be unrelated to the vaccine and excludes latent consequences that may be related to the vaccine. Another solution is to relax the burden of proof to some minor degree in recognition of the evidentiary problems that claimants face. Claimants may be required to prove that there is a "real possibility" that the vaccine caused the serious disability. "Real possibility" suggests a lower threshold than the balance of probabilities but still requires some evidence to support the connection between the vaccine and the disability.

RECOMMENDATION 4

That compensation be payable in respect of death and serious adverse mental or physical consequences where the evidence suggests that there is a real possibility that the adverse consequences were caused by a vaccination.

E. COMPENSATION

The compensation payable to claimants with serious vaccine-related injuries and to family members of those dying as a consequence of a vaccine may be calculated in a variety of ways. First, compensation may be calculated on tort principles. This is the most generous measure of compensation but it has some disadvantages including the difficulty, time and expense of personalized assessments as required in the tort process and its inconsistency with other no-fault schemes in the province which do not use tort principles. It might also be perceived as inconsistent with the policy to provide adequate and reasonable rather than lavish compensation. It must be kept in mind that the compensation paid is a direct charge on the public purse. Furthermore, the generosity of the tort measure is more appropriate in a fault system where the damage award carries the responsibility not only of compensating the plaintiff but also of providing some deterrence to and punishment of the wrongdoer.

Secondly, a standard lump sum may be paid to each successful claimant as an *ex gratia* payment. This is objectionable on the grounds that it fails to distinguish between dissimilar injury and dissimilar need.

Thirdly, the model of Québec may be followed. The assessment of benefits may be made in accordance with the rules of another provincial no-fault compensation scheme. This has the attraction of administrative ease and economy and it adopts an assessment process which is in accordance with declared provincial policy in respect of the victims of other fault-free conduct. The most appropriate model in Manitoba is the *Personal Injury Protection Plan* of Autopac. The various benefits which are payable under that plan appear to provide reasonable and adequate compensation for vaccine-injured children and the families of children who have died because of a vaccination. The main heads of compensation are an income replacement indemnity, student indemnity, medical expenses, rehabilitation expenses, personal care expenses, death benefits including funeral expenses, special expenses and permanent impairment payments. A more detailed description of the available benefits is found in Appendix H. Administrative efficiency could be enhanced by an agreement between Manitoba Health and Autopac under which the latter would pay the compensation to successful claimants.

RECOMMENDATION 5

That compensation for compensable vaccine-related injuries be calculated in accordance with the pertinent assessment rules under the Personal Injury Protection Plan of Autopac.

F. PROCEDURES

The first issue that arises in respect of the procedures for implementing the compensatory plan is the selection of the institution most suited to administer the program. A discrete administrative tribunal may be established such as a Childhood Vaccination Injury Compensation Board with its own staff and procedures. However, this may not be warranted. It is unlikely that there will be a sufficient number of claims to warrant the expense of an independent bureaucracy. The better model is that of Québec and the United Kingdom where existing branches of government have been used to deliver compensation to vaccine-injured children. A useful model which may be modified to apply to the field of vaccine injury compensation is found in those parts of *The Victims' Rights Act*[1] dealing with the no-fault compensation of the victims of crime. There is in that Act a three stage adjudicative process. The Minister of the Crown designated to administer the Act designates an employee under the administration of the minister as the Director of Victims' Support Services who, *inter alia*, hears and determines claims and calculates the appropriate compensation in accordance with the rules and regulations of the Act. The claim form sets out the factual basis for an award of compensation. The Director has wide ranging investigative powers to secure necessary evidence and information to render a decision. No hearing is conducted at this stage. Written notice of the decision must be given to the applicant. An unsuccessful claimant may request a reconsideration of the decision by the Director and may provide additional information to the Director. If the decision rejecting the claim is confirmed, further appeal may be made to the Compensation Appeal Board which conducts hearings and may confirm, vary or rescind the decision of the Director. Members of the Board have the powers of a Commissioner under Part V of *The Manitoba Evidence Act*.[2] The Board may request the assistance of experts. The Board's decision must be given with written reasons.

With appropriate modifications, a similar procedural process could be utilized in respect of vaccine injuries. The government department most suited to administer a *Childhood Vaccination Injury Compensation Act* is that of Health. The Minister would appoint an employee of Manitoba Health with appropriate medical expertise as the Director of Childhood Vaccination Injury Compensation who would handle vaccine injury claims and, upon appropriate investigation and study, determine the eligibility of the claimant under the Act. The powers and procedures of the Director would be similar to those of the Director of Victims' Support Services with

---

[1] *The Victims' Rights* Act, S.M. 1998, c. 44, C.C.S.M. c. V55.

[2] *The Manitoba Evidence Act*. C.C.S.M. c. E150.

appropriate modifications as necessary. Procedures to facilitate a reconsideration by the Director of a rejected claim would also seem to be a wise intermediate step before a formal appeal. The claimant may be able to bring additional information on an informal basis which may lead to some change in the initial decision. This would be followed by an appeal to an independent administrative tribunal known as the Childhood Vaccination Injury Compensation Appeal Board. The membership of the Board would include persons with expertise in immunology, lawyers and lay persons. The Board would hold a hearing giving the claimant a right to be represented and to present evidence. The board members would have the powers of a commissioner under *The Manitoba Evidence Act*. The Board would additionally have the power to seek the assistance of experts and would be encouraged to adopt a pro-active investigative role in determining the appeal. It would have the power to confirm, vary or reverse the decision of the Director. The reasonable costs of claimants should be paid by the Board whether or not they win or lose unless the appeal is totally without merit.

RECOMMENDATION 6

***That the administrative structure and procedures under* The Childhood Vaccination Injury Compensation Act *be modelled insofar as is appropriate on the manner in which no-fault compensation claims are handled under* The Victims' Rights Act.**

G. APPEALS

Final resort to the courts on issues of law and jurisdiction is appropriate. Factual issues should be resolved conclusively by the expertise of the administrative appeal board. The appeal should be to the Manitoba Court of Queen's Bench.

RECOMMENDATION 7

That provision be made that an appeal may be taken from the Childhood Vaccination Injury Compensation Board to the Court of Queen's Bench on issues of law or jurisdiction.

H. FUNDING

The number of funding options are limited in a system of socialized medicine. A parental charge for each vaccination is probably impermissible as a user charge on health care and in any event it would present an undesirable obstacle to optimal rates of immunization. A surtax on the manufacturers of vaccines is impractical because the manufacturers are outside the province and in any event the tax would be passed on to the purchaser who is the provincial government. The realistic option is to make the cost of the scheme a charge on general tax revenues. This has the

added advantage of spreading the cost in the widest manner throughout society which, as a whole, secures to benefits of the childhood immunization program.

RECOMMENDATION 8

That the cost of the Childhood Vaccination Compensation Injury Plan be met from general taxation revenues through an allocation to Manitoba Health.

I. LIMITATIONS

Reasonable limitation periods are important to insure that a claim is assessed at a time when the best evidence, both documentary and from witnesses, is most readily available and most reliable. Limitations raise special difficulties in respect of vaccine injuries. There may a great deal of medical and scientific debate as to whether a disability is a vaccine injury and care must be taken not to rule out latent damage which may become apparent some considerable time after the vaccination. A key issue is the choice of the event from which the time limitation will commence. In cases of fatalities, the conventional choice is the date of death. There are more options in respect of disabilities. Time may run from the date of the vaccination, the onset of symptoms or the date of diagnosis of an injury or illness. The most generous rule is that of the date of diagnosis. The length of time to be given to file a claim is to some degree arbitrary but six years would appear to be a maximum period. A relatively generous limitation period is warranted by possible medical uncertainty as to the cause of the death or injury. A separate limitation period would apply to those claims that had arisen before the date of implementation of the proposed *Childhood Vaccination Injury Compensation Act* if retroactive claims are permitted (see section K below).

RECOMMENDATION 9

That a claim must be brought under the proposed* Childhood Vaccination Injury Compensation Act *within six years of death or the diagnosis of the injury or illness complained of.

J. TORT CLAIMS

There does not appear to be a pressing case for the removal of tort rights. The history of tort litigation in the field of vaccines suggests that litigation in respect of vaccine injuries will be infrequent. If negligence of a manufacturer or a health care professional can be established there is no reason to restrict the claim. The continuing threat of tort liability may contribute to some degree to the quality of the product and the quality of the services of those administering it. If a tort action is successful, the moneys received should be applied first to the plaintiff's cost of the litigation, then to reimburse the no-fault fund in respect of benefits that have been paid to the

successful plaintiff and then to the advantage of the plaintiff. If a claimant refuses to press a viable tort claim, the Director of Childhood Vaccination Injury Compensation should have a right of subrogation. Such a process would model that under *The Victims' Rights Act*.

RECOMMENDATION 10

That there be no restriction on tort claims for childhood vaccine injuries. After the payment of the plaintiff's litigation costs, reimbursement shall be made to the no-fault fund for benefits received. Where a claimant refuses to press a tort claim, an action may be commenced by and in the name of the Director of Childhood Vaccination Injury Compensation.

K. RETROACTIVE CLAIMS

Fairness and justice suggest that all persons in the province who suffered vaccine-related injuries in childhood should be compensated. It does not appear that anyone has been compensated under the tort system and it is unlikely that compensation from other sources has been secured. There is, therefore, an equality of need among all victims varying only in the degree of seriousness of the injury. Justice has already been delayed unduly for vaccine-damaged children. Other jurisdictions responded much more quickly to their plight, beginning as early as 1961 (Germany) to initiate special compensatory plans. It seems unfair that justice may not only be delayed but that it could be denied for so many by the arbitrary date of implementation of the Act.

On the other hand, the older the claim the more difficult it is to process. Records may be lost and witnesses may be unavailable. Furthermore, unlimited access to the fund for historic claims may pose too great a financial burden for government to contemplate.

On balance, all persons suffering vaccine damage in childhood should be compensated. It is recognized that some claims may fail because of an insufficiency of evidence. Furthermore, a more restrictive limitation period for the bringing of retroactive claims is advisable.

RECOMMENDATION 11

That compensation be paid in respect of children who suffered a vaccine-related death or a vaccine injury before the implementation of* The Childhood Vaccination Injury Compensation Act *provided the claim is brought within six years of the coming into force of the Act.

L. ADDITIONAL ISSUES

The focus of this Report is primarily on the need for a targeted no-fault compensation scheme for vaccine-related injuries and death. In the course of our preparation of this Report, two further related issues emerged. They are of particular concern to some interested members of the public. The first concerns informed consent and the second deals with the reporting of adverse consequences of vaccinations.

1. Informed Consent

There is a common perception that parents do not receive sufficient information in respect of the risks and benefits of vaccines and the risks of the illnesses they are intended to prevent and that this might be remedied by a legislative provision mandating physicians and public health nurses to provide full and frank information of this kind. Although, as far as we know, there are no data available to support the anecdotal evidence of a failure to communicate fully all relevant information, it is a complaint that is quite frequently heard. However, as we pointed out earlier in our Report, there is a clear and well established common law duty to secure an informed consent prior to any medical procedure. If there is a problem, it seems more to do with the failure to observe that legal duty rather than a lack of legal obligation. Furthermore, a failure to secure an informed consent is likely to be regarded as professional misconduct potentially subjecting the health care professional to the disciplinary procedures of his or her profession. It is not clear, therefore, that a legislative provision to the same effect would influence the conduct of health care professionals. It is also not clear what sanction would be appropriate for a failure of compliance with the statute. On the other hand, a legislative requirement that mirrors the common law duty, as is found in Ontario, is unlikely to do any harm and it may alert health care professionals to the importance of good information and the contribution that it makes to the integrity of the system of routine childhood immunization.[3] An alternative administrative approach has been adopted by the Department of Health and Community Services in New Brunswick. It has developed Immunization Protocol Forms (copies of which can be found in Appendix I) to encourage and facilitate informed consent. It is a check list to be completed by the administrator of the vaccine which indicates, *inter alia*, that full information has been given about the risks and benefits of both the vaccine and the risks of the illness it is designed to prevent, that an opportunity was given for questions and that the vaccination was not given before the consent provider had a full understanding of the procedure and had given an informed consent. A similar protocol could be developed by Manitoba Health.

The Commission is strongly supportive of the common law duty of informed consent. In

---

[3]There have been a number of unsuccessful private members' bills introduced into the Manitoba Legislature calling for, among other things, a statutory duty to inform patients of risks associated with vaccines: see, e.g., Bill 209, *The Public Health Amendment Act*, 4th session, 35th Legislature, 41 Eliz. II, 1992 and Bill 216, *The Public Health Amendment Act*, 6th session, 35th Legislature, 43 Eliz. II, 1994.

its view, the provision of full and complete information of the risks and benefits of immunization to parents is essential to the integrity of and the confidence in the childhood immunization program. No interest is served by minimizing risks or withholding information. Actions of that nature enhance anxiety, create suspicion and generate criticism, all of which ultimately undermine public confidence and support in the immunization system. The immunization program is only strengthened by a transparency of its purpose, risks and benefits. In the Commission's view, it is advisable that both government and professional associations in the health care field take increased steps to insure observance of the common law duty of informed consent so that full and complete information about childhood vaccination is made available in a timely and complete manner. The Commission is, however, also of the opinion that the passage of a legislative fiat is unlikely to create measurable improvement in the flow of information. That will be achieved only by all involved in the administration of the system including Manitoba Health and the professional associations in the field. They are the ones best placed to provide the necessary leadership and to establish confidence in this respect.

RECOMMENDATION 12

That all persons involved in the system of childhood immunization provide to parents full and accurate information of the risks and benefits of each vaccine and the risks of the disease it is intended to prevent. It urges both Manitoba Health and the pertinent professional associations including the College of Physicians and Surgeons and the Manitoba Association of Registered Nurses to adopt a pro-active role and introduce initiatives involving their members that will increase public understanding of the risks and benefits of immunization and, thereby, increase confidence in the whole process.

2. Reporting of Adverse Events

The second issue relates to the lack of any system in Manitoba of compulsory reporting of adverse consequences temporally related to vaccines similar to that in Ontario. As described earlier, Manitoba relies on a voluntary system of reporting to local medical officers who relay the information to Manitoba Health.[4] There is anecdotal opinion that the reporting of adverse events in Manitoba is incomplete and that reporting may be restricted to those situations where a physician perceives a causal link rather than a temporal association between the vaccine and the adverse event. The opinion has been expressed that a mandatory system would assist in more effectively identifying the full extent of adverse consequences following vaccines. Physicians and other health care professionals could be *required* to fill out a Report of a Vaccine-Associated Adverse Event similar to that found in Appendix B for all such events and forward it to the local

---

[4]Several unsuccessful private members' bills have been introduced into the Manitoba Legislature that would impose a duty on those administering an immunizing agency to report selected reactions to vaccines to the Minister of Health within seven days: see, e.g. Bill 216, *The Public Health Amendment Act 1992*.

medical officer of health or to some other official of Manitoba Health. However, it has been observed that the Ontario system does not operate any more effectively than the voluntary system.[5] The Commission is handicapped in its consideration of this issue by a lack of hard evidence of the extent of the problem. Intuitively, the maximization of information in respect of temporally related adverse events would appear to be entirely beneficial. It further contributes to the sum of knowledge available to both public authorities and the consumers of vaccines which permits everyone to make an informed decision in the matter at issue. It will also facilitate the operation of the childhood compensation plan by assisting to identify the kind of risks associated with particular vaccines. Nevertheless, a statutory duty is a blunt instrument of public policy in this arena. If there is a problem, it is likely to be a systemic and attitudinal one rather than one that might be neatly and fully resolved by a statutory directive. Consequently, the Commission prefers to alert both Manitoba Health and the professional associations in the field to the importance of information of temporally related adverse events and to urge them to undertake all necessary initiatives to maximize the flow of information from those who administer the vaccines to the appropriate authorities.

RECOMMENDATION 13

That Manitoba Health and the professional associations involved in the administration of vaccines take all necessary steps to promote full and complete reporting of all adverse events temporally related to vaccines.

---

[5] *Canadian National Report on Immunization, 1996*, Chapter 9 - "Surveillance of Adverse Events Temporally Associated with Vaccine Administration", 9.2 - "Surveillance Systems":
http://www.hc-sc.gc.ca/hpb/lcdc/publicat/ccdr/97vol23/imm_sup/imm_j_e.html#two

CHAPTER 7

LIST OF RECOMMENDATION

1. That a statute entitled *The Childhood Vaccination Injury Compensation Act* be enacted in Manitoba establishing a compensation plan for vaccine-damaged children. (p. 33)

2. That coverage be given to all persons who are vaccinated under the age of 18 provided that the vaccination was administered in Manitoba by a registered health care professional and the child was a resident in Manitoba at the time of the vaccination. (p. 34)

3. That, within a reasonable time after the implementation of *The Childhood Vaccination Injury Compensation Act*, the government give consideration to the extension of the plan to cover all vaccine recipients. (p. 34)

4. That compensation be payable in respect of death and serious adverse mental or physical consequences where the evidence suggests that there is a real possibility that the adverse consequences were caused by a vaccination. (p. 36)

5. That compensation for compensable vaccine-related injuries be calculated in accordance with the pertinent assessment rules under the Personal Injury Protection Plan of Autopac. (p. 37)

6. That the administrative structure and procedures under *The Childhood Vaccination Injury Compensation Act* be modelled insofar as is appropriate on the manner in which no-fault compensation claims are handled under *The Victims' Rights Act.* (p. 38)

7. That provision be made that an appeal may be taken from the Childhood Vaccination Injury Compensation Board to the Court of Queen's Bench on issues of law or jurisdiction. (p. 38)

8. That the cost of the Childhood Vaccination Injury Compensation Plan be met from general taxation revenues through an allocation to Manitoba Health. (p. 39)

9. That a claim must be brought under the proposed *Childhood Vaccination Injury Compensation Act* within six years of death or the diagnosis of the injury or illness complained of. (p. 39)

10. That there be no restriction on tort claims for childhood vaccine injuries. After the payment of the plaintiff's litigation costs, reimbursement shall be made to the no-fault fund for benefits received. Where a claimant refuses to press a tort claim, an action may be commenced by and in the name of the Director of Childhood Vaccination Injury Compensation. (p. 40)

11. That compensation be paid in respect of children who suffered a vaccine-related death or a vaccine injury before the implementation of *The Childhood Vaccination Injury Compensation Act* provided the claim is brought within six years of the coming into force of the Act. (p. 40)

12. That all persons involved in the system of childhood immunization provide to parents full and accurate information of the risks and benefits of each vaccine and the risks of the disease it is intended to prevent. It urges both Manitoba Health and the pertinent professional associations including the College of Physicians and Surgeons and the Manitoba Association of Registered Nurses to adopt a pro-active role and introduce initiatives involving their members that will increase public understanding of the risks and benefits of immunization and, thereby, increase confidence in the whole process. (p. 42)

13. That Manitoba Health and the professional associations involved in the administration of vaccines take all necessary steps to promote full and complete reporting of all adverse events temporally related to vaccines. (p. 43)

This is a Report pursuant to section 15 of *The Law Reform Commission Act*, C.C.S.M. c. L95, signed this 28th day of June 2000.

Clifford H.C. Edwards, President

John C. Irvine, Commissioner

Gerald O. Jewers, Commissioner

Pearl K. McGonigal, Commissioner

Kathleen C. Murphy, Commissioner

APPENDIX A

Canadian Immunization Guide Fifth Edition 1998

Comparison of effects of diseases and vaccines

Disease		Effects of Disease	Side Effects of Vaccine
Incidence Before Vaccination	**Incidence After Vaccination**		
Polio Spread by faeces and saliva. Incubation: 1-2 weeks. Infection may lead to fever, headache, nausea and vomiting, muscle weakness and paralysis.		1% of infections have clinical symptoms, but about 1 in 20 hospitalized patients dies and 50% of survivors remain paralyzed.	IPV used in Canada so vaccine-associated polio, though very rare, is no longer a risk. Local discomfort or inflammation in 5% of recipients – see side effects of DTaP vaccine below for combination use
Range 2.5 - 28.3 /100,000. Epidemic years had up to 20,000 cases of paralytic disease	Indigenous disease eradicated from the Americas. Still endemic in other parts of the world.		
Diphtheria Spread by nasal droplets. Incubation: 2-5 days. Infection leads to severe pharyngitis and cervical adenopathy. Patient is infectious for up to 2 weeks.		Case fatality rate 5-10%. Toxin may lead to myocardial and neurologic complications.	DTaP vaccine – about 20% have local discomfort or inflammation, 5% have fever. A transient nodule may develop at the injection site, lasting a few weeks. Up to 70% at the 4-6 yr booster develop redness and swelling.
Highest in 1924 with 9,000 cases that year.	Now 2-5 reported cases per year, none reported in 1996.		
Tetanus Bacteria present in soil and animal faeces. Incubation: 3-21 days. Causes painful muscular contractions and convulsions.		Case fatality about 10%. Risk is greatest for the very young or old.	See above – side effects of DTaP vaccine. Local erythema and swelling not uncommon with adult boosters, and increasing with age. Peripheral neuropathies have been rarely reported.
Average 40-50 deaths per year.	3-5 cases per year reported, only 5 deaths in the last 18 years and none since 1991.		
Pertussis Spread by cough and nasal droplets. Incubation: 7-10 days. Symptoms include runny nose and irritating cough, which may develop into whooping cough.		About 1% case fatality in patients under 6 months, from pneumonia or fatal encephalopathy (usually hypoxic). Several deaths still occur every year, particularly in unimmunized infants.	See above – side effects of DTaP vaccine. Rate of reactions to acellular pertussis vaccine is less than with whole cell.
Average 153 /100,000.	Average 10 /100,000.		
Hib Spread by nasal droplets. Incubation: 2-4 days. Presents as an acute illness with fever, vomiting, and lethargy (symptoms of meningitis) in 55-65%. In the remainder, it can also cause epiglottitis, pneumonia, bacteremia and other complications.		Case fatality of meningitis is 5% (10-15% of survivors have permanent neurologic sequelae and 15-20% have deafness).	5% have discomfort or local inflammation, 2% have fever. Usually given in combination with DTaP (see above – side effects of DTaP vaccine)
Leading cause of bacterial meningitis in infancy. About 2,000 cases per year.	Only anecdotal cases now being reported, less than 60 cases per year in the last few years.		
Measles Spread by cough and nasal droplets. Incubation: 1-2 weeks. Symptoms include fever, sore throat, cough, runny nose, itchy eyes and a red rash that starts on the face and spreads to the rest of the body		Complications such as bronchopneumonia and otitis media in about 10%. 1/1,000 encephalitis (case fatality 10%, permanent sequelae 25%). 1/25,000 develops SSPE.	5-10% have discomfort, local inflammation or fever with or without a non-infectious rash. 1/1 million recipients develop encephalitis. About 1/24,000 develop transient thrombocytopenia.
Cyclic with increasing incidence every 2-3 years. About 300 to 400,000 cases per year estimated.	Recent outbreaks with 11,000 cases (1989) and 2,300 (1995). With 2 dose schedule, now less than 400 cases per year.		
Mumps Spread by saliva. Incubation: 2-3 weeks. Symptoms include fever and parotitis.		1/ 200 children develops encephalitis. 20-30% of post-pubertal males develop orchitis, 5% of females develop oophoritis. Occasionally, mumps causes infertility or deafness.	Fever and a mild skin rash occasionally occurs. 1% of recipients may develop parotitis. 1/3 million recipients may develop aseptic meningitis.
Highest in 1942 with 52,344 cases. Average incidence 136 /100,000.	Average incidence 2.35 /100,000, or about 500 cases annually.		
Rubella Spread by nasal droplets. Incubation: 2-3 weeks. Symptoms include fever, headache, itchy eyes, cervical adenopathy and rash.		50% develop a rash and adenopathy, 50% of adolescents and adults have acute arthralgias or arthritis. 1/6,000 develops an encephalopathy. Infections in the first 10 weeks of pregnancy have an 85% risk of CRS.	About 10% have discomfort, local inflammation or fever. About 5% have swollen glands, stiff neck or joint pains. About 1% develop a noninfectious rash. Transient arthralgias or arthritis may occur, more in post-pubertal females.
Highest in 1936 with 69,401 cases. Average 149 /100,000.	Average of 8.5 /100,000. About 2,000 cases reported annually.		

APPENDIX B

Health Canada / Santé Canada

REPORT OF A VACCINE-ASSOCIATED ADVERSE EVENT

Protected when completed

In confidence to: Division of Immunization
L.C.D.C., Tunney's Pasture 0603E1
Ottawa, Ontario K1A 0L2
(613) 957-1340 1-800-363-6456 FAX (613) 998-6413

IDENTIFICATION

PATIENT IDENTIFIER	PROVINCE/TERRITORY	DATE OF BIRTH (YEAR / MONTH / DAY)	SEX (☐ Male ☐ Female)	DATE OF VACCINE ADMINISTRATION (YEAR / MONTH / DAY)

VACCINES

VACCINE(S) GIVEN	NUMBER IN SERIES	SITE	ROUTE	DOSAGE	MANUFACTURER	LOT NUMBER

ADVERSE EVENT(S)

Events marked with an * (asterisk) must be diagnosed by a PHYSICIAN. Report only events which cannot be attributed to co-existing conditions. Additional information for all events should be provided under SUPPLEMENTARY INFORMATION on reverse side. Record interval between vaccine administration and onset of each event in minutes, hours or days.

LOCAL REACTION AT INJECTION SITE

☐ **INFECTED ABSCESS** (tick one or both of the options below) — MIN / HOURS / DAYS
(i) positive gram stain or culture ☐
(ii) existence of purulent discharge with inflammatory signs ☐

☐ **STERILE ABSCESS/NODULE** — MIN / HOURS / DAYS
No evidence of acute microbiological infection

☐ **SEVERE PAIN AND/OR SEVERE SWELLING** — MIN / HOURS / DAYS
(tick one or both of the options below)
(i) lasting 4 days or more ☐
(ii) extending past nearest joint(s) ☐

☐ **SCREAMING EPISODE/PERSISTENT CRYING** — MIN / HOURS / DAYS
Inconsolable for 3 hours or more; OR quality of cry distinctly abnormal for child and not previously heard by parents

☐ **FEVER** — MIN / HOURS / DAYS
Highest recorded temperature (Report only 39.0°C (102.2°F) or above)
Temperature ___ . ___ °C (or _____ °F)
Site: rectal ☐ oral ☐ axilla ☐ skin ☐ tympanic ☐
Temperature believed to be high but not recorded ☐
Should be supported by the presence of other systemic symptoms

☐ **ADENOPATHY** (tick one or both of the options below) — MIN / HOURS / DAYS
(i) enlarged lymph node(s) ☐
(ii) drainage of lymph node(s) ☐
Site(s) _____

☐ **PAROTITIS** — MIN / HOURS / DAYS
Swelling with pain and/or tenderness of parotid gland(s)

* ☐ **ANAPHYLAXIS OR SEVERE SHOCK** — MIN / HOURS / DAYS
Explosive, occurring within minutes after immunization, and evolving rapidly towards cardiovascular collapse AND requiring resuscitative therapy

☐ **OTHER ALLERGIC REACTIONS** (tick one or more of the options below) — MIN / HOURS / DAYS
(i) wheezing or shortness of breath due to bronchospasm ☐
(ii) swelling of mouth or throat ☐
(iii) skin manifestations (e.g., hives, eczema, pruritus) ☐
(iv) facial or generalized edema ☐

☐ **RASHES** (other than hives) — MIN / HOURS / DAYS
Lasting 4 days or more AND/OR requiring hospitalization
Generalized ☐ Localized (indicate site) ☐ _____
Specify characteristics of rash _____

☐ **ARTHRALGIA/ARTHRITIS** — MIN / HOURS / DAYS
Joint pain/inflammation lasting at least 24 hours
If condition is an acute exacerbation of a pre-existing diagnosis, give details under Supplementary Information

☐ **SEVERE VOMITING AND/OR DIARRHEA** — MIN / HOURS / DAYS
Must be severe enough to interfere with daily routine

☐ **HYPOTONIC-HYPORESPONSIVE EPISODE** (in children < 2 yrs. only) — MIN / HOURS / DAYS
Characterized by all the features of: (i) generalized decrease/loss of muscle tone; AND (ii) pallor or cyanosis; AND (iii) decreased level of awareness or loss of consciousness
Should not be mistaken for fainting, a post-convulsion state or anaphylaxis

☐ **CONVULSION/SEIZURE** — MIN / HOURS / DAYS
Febrile ☐ Afebrile ☐
Past History of: A) Febrile seizures Yes ☐ No ☐
B) Afebrile seizures Yes ☐ No ☐
Omit fainting, seizures occurring within 30 minutes of immunization, and seizures occurring as part of encephalopathy or meningitis/encephalitis

* ☐ **ENCEPHALOPATHY** — MIN / HOURS / DAYS
Acute onset of major neurological illness characterized by any two or more of: (i) seizures; (ii) distinct change in level of consciousness or mental status (behaviour and/or personality) lasting 24 hours or more; (iii) focal neurological signs which persist for more than 24 hours

* ☐ **MENINGITIS AND/OR ENCEPHALITIS** — MIN / HOURS / DAYS
Abnormal CSF findings AND an acute onset of: (i) fever with neck stiffness or positive meningeal signs; OR (ii) signs and symptoms of encephalopathy (see ENCEPHALOPATHY above)
Results of CSF examination should be provided under Supplementary Information

* ☐ **ANAESTHESIA/PARAESTHESIA** — MIN / HOURS / DAYS
Lasting over 24 hours
Generalized ☐ Localized (indicate site) ☐ _____

* ☐ **GUILLAIN-BARRÉ SYNDROME** — MIN / HOURS / DAYS
Progressive subacute weakness of more than one limb (typically symmetrical) with hyporeflexia/areflexia

* ☐ **PARALYSIS** (Do not code if Guillain-Barre Syndrome is coded) — MIN / HOURS / DAYS
Limb paralysis ☐ Facial or cranial paralysis ☐
Describe _____

* ☐ **THROMBOCYTOPENIA** — MIN / HOURS / DAYS
Give lab results under Supplementary Information

☐ **OTHER SEVERE OR UNUSUAL EVENTS** — MIN / HOURS / DAYS
Include any adverse event believed to be related to immunization, that does not fit any of the categories listed above and for which no other cause is clearly established
Report events of clinical interest which require medical attention, and particularly events that are (i) fatal, (ii) life-threatening, (iii) require hospitalization, or (iv) result in residual disability

DESCRIPTION

REPORTER'S NAME	TELEPHONE NUMBER ( )	ADDRESS (Institution/No., Street, etc.)
PROFESSIONAL STATUS: MD ☐ RN ☐ OTHER _____		City / Province / Postal Code
SIGNATURE	DATE: Year / Month / Day	

Canada

HC/SC 4229 (03-96) · 1

OUTCOME OF EVENT(S) AT TIME OF REPORT PLEASE FORWARD ANY FOLLOW UP INFORMATION	FULLY RECOVERED ☐	RESIDUAL EFFECTS (describe) ☐	FATAL ☐	LOST TO FOLLOW-UP ☐	PENDING ☐	
SOUGHT MEDICAL ATTENTION (Emergency room, clinic, family physician etc.)	NO ☐	YES ☐	(If yes, include relevant details of treatment under Supplementary Information)			
HOSPITALIZED BECAUSE OF EVENT(S)	NO ☐	YES ☐	**LENGTH OF STAY** (DAYS)	**DATE ADMITTED**	Year	Month Day

CONCOMITANT MEDICATIONS (exclude those used to treat the adverse event) DRUG(S) GIVEN	**MEDICAL HISTORY** Please provide information on relevant medical history or concurrent illness (See detailed instructions on reverse)

SUPPLEMENTARY INFORMATION

INSTRUCTIONS FOR COMPLETING REPORT OF A VACCINE-ASSOCIATED ADVERSE EVENT

1. Please use dark ink when completing form to improve legibility of copies.
2. Report only events which have a temporal association with a vaccine and which cannot be attributed to co-existing conditions. **A causal relationship does not need to be proven, and submitting a report does not imply causality.**
3. Events marked with an asterisk (*) must be diagnosed by a physician. Supply relevant details in the SUPPLEMENTARY INFORMATION box.
4. Record interval between vaccine administration and onset of each event in minutes, hours or days.
5. Provide relevant information, when appropriate, in the SUPPLEMENTARY INFORMATION box. Includes details of events diagnosed by physician (see 3 above), results of diagnostic or laboratory tests, hospital treatment, and discharge diagnoses where a vaccinee is hospitalised because of a vaccine-associated adverse event. If appropriate, and preferred, photocopies of original records may be submitted.
6. Provide details of medical history that are relevant to the adverse event(s) reported. Examples include a history of allergies in vaccinee, previous adverse event(s), and concurrent illnesses which may be associated with the current adverse event(s)

TO BE COMPLETED BY MEDICAL HEALTH OFFICER RECOMMENDATIONS FOR FURTHER IMMUNIZATION

NAME: _____ PHONE: _____

SIGNATURE **DATE** Year Month Day

APPENDIX C

Manitoba Immunization Schedule

Manitoba Health
Public Health Branch

COMMUNICABLE DISEASE CONTROL

Manitoba Routine Immunization Schedule for Infants and Children

	Vaccines				
Age at Immunization	DaPTP	Hib	MMR'	Td	IPV
2 months	X	X			
4 months	X	X			
6 months	X	X			
12 months			X		
18 months	X	X			
5 years	X*		X		
15 years				X	X#

Manitoba Immunization Schedule for Children ≥ 7 years who have not received previous immunizations

	Vaccines		
Age at Immunization	Td	IPV	MMR'
First visit	X	X	X
2 months later	X	X	X
6-12 months after 2nd visit	X	X	
10 years after 3rd visit	X		

DaPTP = diphtheria, acellular pertussis, tetanus, inactivated polio
Hib = haemophilus influenzae B (PRP-T)
MMR = measles, mumps, rubella
Td = tetanus; adult diphtheria formulation
IPV = inactivated polio

* Not required if the fourth dose was given after the fourth birthday.

\# Required only if **all** previous immunizations have been with IPV. Future studies with children who have received all previous doses with enhanced IPV may show that this dose of IPV is no longer necessary. Can be given together with tetanus and diphtheria as TdPolio vaccine.

' Children born 1985-1990 inclusive were offered a second dose of measles vaccine in a mass campaign in October 1996. Those who missed this dose should be immunized with a second dose of MMR or MR as opportunities arise.

Manitoba Immunization Schedule for Children <7 years Not Immunized in Early Infancy

Age at Immunization	Vaccines				
	DaPTP	Hib^◊	MMR+	Td	IPV
First visit	X	X	X		
2 months later	X				
2 months after 2nd visit	X				
6-12 months after 3rd visit	X				
5 years	X*		X		
15 years				X	X#

DaPTP = diphtheria, acellular pertussis, tetanus, inactivated polio
Hib = haemophilus influenzae B (PRP-T)
MMR = measles, mumps, rubella
Td = tetanus; adult diphtheria formulation
IPV = inactivated polio

\+ Given at 12 months of age or older.

* Not required if the fourth dose was given after the fourth birthday.

\# Required only if **all** previous immunizations have been with IPV. Future studies with children who have received all previous doses with enhanced IPV may show that this dose of IPV is no longer necessary. Can be given together with tetanus and diphtheria as TdPolio vaccine.

^ Number of doses of Hib depends on age at which immunization begins:
2-6 months: 3 doses 2 months apart with booster at 15-18 months
7-11 months: 2 doses 2 months apart with booster at 15-18 months
12-14 months: 1 dose with booster at 15-18 months
15-59 months: 1 dose
60 months and older: no doses required
Booster dose should be given at least 2 months after preceding dose.

◊ Children with a lapse in administration should be immunized as follows:

Age at presentation	Prior immunization history	Number of doses required
7-11 months	1 dose	1 dose with booster at 15-18 months
	2 doses	same as above
12-14 months	1 dose	1 dose and booster at 15-18 months
	2 doses	1 dose
15-59 months	any incomplete schedule	1 dose

Doses should be given a minimum of 2 months apart.

APPENDIX D

Vaccine Injury Compensation Programs Worldwide*

	Germany	France	Japan	Switzerland	Denmark	New Zealand	Sweden	United Kingdom	Quebec	United States	Taiwan	Italy	Norway
Enacted	1961	1964	1970 (1977)	1970	1972 (1978)	1974	1978	1979	1985	1988	1988	1992	1995
Administrative Entity	state (Länder) pension system (federal law guides outcome)	Ministry of Solidarity, Health and Welfare	Ministry of Health and Welfare	state (Canton) (federal law guides outcome)	National Social Security Office (NSSO)	Accident Rehabilitation & Compensation Insurance Corp (semi-govt.)	Insurance (voluntary, non-governmental)	Department of Social Security	Ministry of Health and Social Services	Department of Health and Human Services (DHHS)	Department of Health	Ministry of Health (managed at various levels)	Ministry of Health and Social Affairs
Vaccines covered	recommended by Länder (most routine & specific use vaccines)	compulsory (HBV, D, T, polio, BCG, typhoid)	recommended (polio, D, M, R, P, JE, and others for control of epidemics)	recommended by Canton (D, T, P, HBV, inf., Hib, M, M, R, polio) (or comp)	government-provided (free) (D, T, P, M, M, R, polio, Hib, BCG)	all that are administered	all prod marketed by Pharmaceutical Insur Assoc & in clinical trials	routine childhood (D, T, P, M, M, R, polio, BCG, Hib)	voluntary (none are required) (D, T, P, M, M, R, BCG, HAV, HBV, typhoid, etc.)	routine childhood (D, T, P, M, M, R, polio, Hib, VZV, HBV, RV)	compulsory (BCG, HBV, OPV, D, T, P, M, M, R, JE, D, T, Inf.) (rec traveler, orphan?)	compulsory (D, T, polio, HBV, typhoid) TBC, typhus/paratyphus	routine childhood (D, T, P, Hib, M, M, R, polio, BCG) (recommended or compulsory)
Filing Deadlines	none	4 years after injury stabilization	no limit	none (individual Cantons may have limits)	1 year after onset of symptoms	1 year (exceptions if claim is incomplete)	3 years after being made first aware of injury 15 yr limit	within 6 years of the latest of either vac. date or age 2	3 years after vacc. or death, or onset of chronic illness	injury: 3 years death: 2 years (after onset of symptoms)	1 year after vaccination	injury: 3 years death: no limit	not specified
Compensable Injuries	injuries exceeding the extent of usual vaccine reactions	all damage directly attributable to vaccination	disability or death resulting from vaccination	injury has to exceed a normal postvaccinal reaction	injuries with reasonable probability caused by vaccine	vaccine-related injury that is rare and severe	those noted as side effect in PASS (like U.S. PDR) or in medical literature	severe disability to extent of 80% or more as a result of vaccination	any serious, permanent damage (physical or mental) including death	injuries listed on the Vaccine Injury Table or by proving causation	table of compensable injuries	death or injury resulting in permanent physical or mental impairment	not specified
Process and Decision-making	claims evaluated by Länder office in charge of social recompensation —utilize medical expert advice	choice of ministerial commission or administrative tribunal	Committee on Public Health decides eligibility and damages	health dept. reviews claim and seeks supporting information	claim reviewed within NSSO—may obtain further information	patient files claim form, reviewed by ACC Medical Misadventure Advisory Committee	claims manager with Zurich Insurance makes decision with medical consultation as needed	claim evaluated by medical officer; makes recommendation to Secretary of State for Social Security	claim reviewed by 3-member Medical Eval Committee; final decision by Minister of Health	DHHS reviews claim and makes recommendation; final decision by US Court of Federal Claims	Vaccine Injury Comfort Fund Working Group, Dept. of Health (17 members--?decision-making)	Medical Hospital Board for eligibility; compensation based on 8 category levels of injury	Ministry of Health decides eligibility
Proof needed	probable cause	clear and convincing evidence	not specified	not specified	reasonable probability	balance of probabilities	balance of probabilities	balance of probabilities	balance of probabilities	balance of probabilities	balance of probabilities	not specified	balance of probabilities
Elements of Compensation	medical costs disability pension, funeral costs	medical costs, disability pension, death benefits, non-economic dam.	medical costs, disability pension, death benefits	medical costs, disability pension, death benefits, non-economic loss	medical costs, death benefits, non-economic damages	medical costs, disability pension, death benefits	unreimbursed medical costs, lost wages, death benefits, pain and suffering	lump sum of payment of statutory sum (40,000 pounds)	unreimbursed medical costs, rehabilitation costs, death benefits	unreimbursed past and future medical expenses, lost wages, non-economic loss, attorneys' fees	medical costs, health care expenses, burial expenses	free medical care, medication, disability pension, death benefit	no precedent (only award to date was a lump sum payment)
Funding Source	general revenues of the Länder	national treasury	treasury (50%) prefecture (25%) municipal (25%)	general revenues of the Canton	national treasury	employers, wage earners, auto licensing fees, govt., invest. income	manufacturers pay premiums into fund	consolidated fund provided by Parliament	national treasury	national treasury (pre-enactment) excise tax on covered vac. (post-enactment)	manufacturers and local society and community	national treasury	national treasury; contribution from manufacturers
Appeal Rights	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	no
Litigation Rights	yes (with limits)	no	yes	yes (with limits)	yes (with limits)	no	no	yes (with limits)	yes	yes (with limits)	yes	yes	yes
Claims Data	Tot 4 589 (76-90) Comp 1 139	Tot 51 (80-98) Comp 37	Tot 2 982 (77-98) Comp 2 720	Tot 1 (70-98) Comp 1	Tot 55 (93-98) Comp 5	Tot 211 (74-99) Accepted 68	Tot 140 (78-98) Comp 79	Tot 4 012 (79-98) Paid 890	Tot 142 (87-98) Comp 17	Tot 5 355 (88-99) Comp 1 390	Tot 123 (88-98) Comp 62	Tot 366 (32-98) Comp 260	Tot 1 Comp 1

*As of June 1999

APPENDIX E

AUTOMOBILE INSURANCE ACT, R.S.Q. c. A-25[1]

INDEMNITY	ENTITLEMENT[2]	AMOUNT[3]
1. Income Replacement Indemnity (Chapter II)	a) Victim who holds regular full time employment (ss.13-17) (Victim must be over the age of 16 and not enrolled in a secondary or post-secondary educational institution on a full time basis)	Salaried victim - computed on the basis of the gross income[4] derived from his employment (or, if the victim proves that he would have held a more remunerative employment but for special circumstances, the indemnity will be calculated on that basis). Self-employed Victim - computed on the basis of the gross income determined by regulation of the Société d'assurance automobile for an employment of the same class, or the amount the victim derives from his work, if it is higher.

[1]The following table comprises a summary of pertinent provisions applicable to persons under the age of 18. All dollar figures have been updated to reflect awards available as of January 1, 2000. These amounts are taken from the Compensation Table of the information booklet, entitled *The Insurance Policy for All Quebecers*, provided by the Société de l'assurance automobile du Québec.

[2]A victim ceases to be entitled to an income replacement indemnity when:
- he becomes able to hold the employment he held at the time of the accident;
- he becomes able to hold the employment he would have held at the time of the accident but for particular circumstances;
- he becomes able to hold an employment determined for him by the Société under s.45;
- one year after becoming able to hold employment determined for him by the Société under s. 46 or 47;
- he holds an employment from which he derives a gross income equal to or greater than the gross income on the basis of which the Société has computed the income replacement indemnity;
-at any other time provided by the Act;
- at his death.

If the victim regains his ability to work but lost his regular full-time or part-time employment due to the accident, the Société shall continue to pay the income replacement indemnity as follows:
- 30 days if the disability lasted for not less than 90 days but not more than 180 days;
- 90 days if the disability lasted more than 180 days but not less than one year;
- 180 days if the disability lasted more than one year but not more than two years;
- one year if the disability lasted more than two years.

[3]See Division IV Computation of Indemnity for more details.

[4]Gross income includes unemployment insurance benefits or allowances paid under the *National Training Act*, R.S.C. 1985, c. N-19.

	b) Victim who holds regular employment on a temporary or part time basis (ss. 18-22) (Victim must be over the age of 16 and not enrolled in a secondary or post-secondary educational institution on a full-time basis)	For the first 180 days after the accident - the amount is determined as in a). As from the 181st day, the Société shall determine an employment for the victim in the manner prescribed by regulation, taking into account the training, work experience and physical and intellectual abilities of the victim on the date of the accident. The Société shall establish the gross income in the manner prescribed by regulation, taking into account the fact that the victim could have held the employment on a full or part-time basis, the work experience of the victim in the five years preceding the accident, the gross income the victim derived from an employment held before the accident. In any event, the gross income shall not be less than the income replacement indemnity the victim received at the end of the 180th day after the accident
	c) Victim unemployed but able to work (ss. 23-26) (Victim must be over the age of 16 and not enrolled in a secondary or post-secondary educational institution on a full-time basis).	For the first 180 days after the accident - the victim is entitled to the indemnity if he would have been able to hold employment or is deprived of employment insurance benefits or allowances paid under the *National Training Act* (NTA). The indemnity is paid for such time as the employment would have been available and for such time as he is unable to hold it or receive the benefits. The amount is Computed on the basis of the gross income or the benefits the victim would have received. As of the 181st day - employment will be determined by the Société as above. The indemnity will not be less than the indemnity the victim was receiving at the end of the 180th day.

	d) Victim is 16 years of age or over in full time attendance at an educational institution (ss.27-33)	Victim is entitled to an indemnity for such time as he is unable to begin or continue his current studies, if they are delayed. The right to the indemnity ceases on the date scheduled at the time of the accident for the completion of his studies. The amount is as follows: - $6,862 for every school year missed at the secondary level; - $6,862 for every term missed at the post-secondary level up to a maximum of $13,726 per year. In addition, the victim is entitled to an income indemnity as follows: - employment insurance benefits or allowances paid under the NTA; Or the greater of: - an indemnity paid for such time as the employment he held would have been available calculated as in a) or, - if after the scheduled date for the completion of his studies, the victim is unable to begin or continue his studies and unable to hold employment, an indemnity computed on the basis of a gross income equal to a yearly average computed on the basis of the average weekly earnings of the Industrial Composite in Québec or, - if the victim resumes his studies but is unable to hold employment after completing or ending his current studies, an indemnity from the date of the end of his studies and for such time as he remains incapacitated. If his studies end before the scheduled date, he is entitled to: - up to the end of the studies, as above;[5] - from the date of the scheduled date of completion, to an income replacement indemnity computed as above.[66]

[5]The amount is as follows:
- $6,862 for every school year missed at the secondary level;
- $6,862 for every term missed at the post-secondary level up to a maximum of $13,726 per year.

[6]*Id.*

	e) Victim is under 16 years of age (ss. 34-39)	Victim is entitled to an indemnity for such time as he is unable to begin or complete his studies. The amount is as follows: - $3,742 for every school year[7] missed at the elementary level; - $6,862 for every school year missed at the secondary level. In addition, the victim is entitled to: - employment insurance benefits; Or the greater of the following: - an income replacement indemnity calculated as in a) if the victim held employment or would have held employment but for the accident; or - an indemnity calculated on the basis of a gross income equal to a yearly average established on the basis of the average weekly earnings of the Industrial Composite in Québec, for the victim who from the end of the school year in which he reached 16 is unable to continue his studies and hold employment; or - if the victim resumes his studies but is unable to hold employment after his studies, he is entitled to an indemnity; or, - if the studies end before the scheduled date, he is entitled to the following amount: - until the date scheduled-- - $3,742 for every school year missed at the elementary level; - $6,862 for every school year missed at the secondary level; - from the date scheduled, he is entitled to an income replacement indemnity calculated as above.[8]
2. Death Benefits (Chapter III)	Victim is a minor and has no dependant on the date of his death.	Parents are entitled to equal shares of a lump sum indemnity of $40,000.

[7] The school year is deemed to commence July 2 and end on June 30 of the following year. Elementary school extends from kindergarten to the sixth grade.

[8] Computed on the basis of a gross income equal to a yearly average computed on the basis of the average weekly earnings of the Industrial Composite in Québec.

3. Non-Pecuniary Damage (Chapter IV)	Physical or mental impairment	Victim is entitled to a lump sum indemnity not exceeding $175,000. Compensation will not be less than $500.[9]
4.Reimbursement of expenses (Chapter V)	a) Personal assistance and care expenses	Maximum of $623 per week paid upon presentation of vouchers or alternatively as a weekly allowance.
	b) General expenses	Exclusive of expenses covered by social security, a victim may be reimbursed for medical and paramedical care, transportation and lodging for the purpose of receiving such care, purchase of prostheses or orthopaedic devices, cleaning, repairs or replacement of clothing he was wearing and which was damaged.

[9]The impairment is evaluated in terms of a percentage determined on the basis of the schedule of permanent impairment established by regulation (s.76).

APPENDIX F

HRSA HEALTH RESOURCES AND SERVICES ADMINISTRATION • HHS
BHPr • BUREAU OF HEALTH PROFESSIONS

National Vaccine Injury Compensation Program
Vaccine Injury Table

(Effective Date: October 22, 1998)

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT; Td, or TT)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Brachial Neuritis	2-28 days
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
II. Vaccines containing whole-cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTaP, DTP, P, DTP-HiB)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Encephalopathy (or encephalitis)	72 hours
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Encephalopathy (or encephalitis)	5-15 days (not less than 5 days and not more than 15 days) for measles, mumps, rubella, or any vaccine containing any of the foregoing as a component.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable

IV. Vaccines containing rubella virus (e.g., MMR, MR, R)	A. Chronic arthritis	7-42 days
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
V. Vaccines containing measles virus (e.g., MMR, MR, M)	A. Thrombocytopenic purpura	7-30 days
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient	6 months
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio	
	-- in a non-immunodeficient recipient	30 days
	-- in an immunodeficient recipient	6 months
	-- in a vaccine-associated community case	Not applicable
	B. Vaccine-Strain Polio Viral Infection	
	-- in a non-immunodeficient recipient	30 days
	-- in an immunodeficient recipient	6 months
	-- in a vaccine-associated community case	Not applicable
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
VII. Vaccines containing polio inactivated virus (e.g., IPV)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Any acute complication sequela (including death) of an illness, disability, injury, or condition referred to above which illness,	Not applicable

	referred to above which illness, disability, injury or condition arose within the time period prescribed	
VIII. Hepatitis B. vaccines	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
IX. Hemophilus influenzae type b polysaccharide vaccines (unconjugated, PRP vaccines)	A. Early-onset Hib disease	7 days
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
X. Hemophilus influenzae type b polysaccharide conjugate vaccines	No condition specified	Not applicable
XI. Varicella vaccine	No condition specified	Not applicable
XII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage	No condition specified	Not applicable

Qualifications and Aids to Interpretation

(1) Anaphylaxis and anaphylactic shock

Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

(2) Encephalopathy

For purposes of the Vaccine Injury Table, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(I) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) **For children less than 18 months of age** who present without an associated seizure event, an acute encephalopathy is indicated by a "significantly decreased level of consciousness" (see "D" below) lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) **For adults and children 18 months of age or older,** an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (2)(I)(A) and (2)(I)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) **Chronic encephalopathy** occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who

return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

(3) Residual Seizure Disorder

A petitioner may be considered to have suffered a residual seizure disorder for purposes of the Vaccine Injury Table, if the first seizure or convulsion occurred 5-15 days (not less than 5 days and not more than 15 days) after administration of the vaccine and 2 or more additional distinct seizure or convulsion episodes occurred within 1 year after the administration of the vaccine which were unaccompanied by fever (defined as a rectal temperature equal to or greater than 101.0 degrees Fahrenheit or an oral temperature equal to or greater than 100.0 degrees Fahrenheit). A distinct seizure or convulsion episode is ordinarily defined as including all seizure or convulsive activity occurring within a 24-hour period, unless competent and qualified expert neurological testimony is presented to the contrary in a particular case.

For purposes of the Vaccine Injury Table, a petitioner shall not be considered to have suffered a residual seizure disorder, if the petitioner suffered a seizure or convulsion unaccompanied by fever (as defined above) before the fifth day after the administration of the vaccine involved.

(4) Seizure and convulsion

For purposes of paragraphs (2) and (3) of this section, the terms, "seizure" and "convulsion" include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(5) Sequela

The term "sequela" means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(6) Chronic Arthritis

For purposes of the Vaccine Injury Table, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination;

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination:

(C) Medical documentation of an antibody response to the rubella virus.

For purposes of the Vaccine Injury Table, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of the Vaccine Injury Table.

(7) Brachial neuritis

Brachial neuritis is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities. Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

(8) Thrombocytopenic purpura

Thrombocytopenic purpura is defined by a serum platelet count less than 50,000/mm^3. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased

number of megakaryocytes in an otherwise normal marrow.

(9) Vaccine-strain measles viral infection

Vaccine-strain measles viral infection is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

(10) Vaccine-strain polio viral infection

Vaccine-strain polio viral infection is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

(11) Early-onset Hib disease

Early-onset Hib disease is defined as invasive bacterial illness associated with the presence of Hib organism on culture of normally sterile body fluids or tissue, or clinical findings consistent with the diagnosis of epiglottitis. Hib pneumonia qualifies as invasive Hib disease when radiographic findings consistent with the diagnosis of pneumonitis are accompanied by a blood culture positive for the Hib organism. Otitis media, in the absence of the above findings, does not qualify as invasive bacterial disease. A child is considered to have suffered this injury only if the vaccine was the first Hib immunization received by the child.

Go to: **DVIC | BHPr | HRSA | HHS**

For additional information call our public information line at 1-800-338-2382.

Last updated 09/10/99

APPENDIX G

Totals:	1,147		405	3,0559	538	5,149

III. Awards Paid (Petitioner's Awards AND Attorney's Fees Only Payments)

	Pre-88	$ in mil	Post-88	$ in mil		Total Awards
FY 1990	91	$ 71.9	0	$ 0.0	91	$71.9
FY 1991	149	$ 75.4	14	$ 4.2	163	$79.6
FY 1992	215	$ 84.5	33	$13.1	248	$97.6
FY 1993	390	$110.4	40	$15.0	430	$125.4
FY 1994	439	$ 85.0	69	$22.0	508	$107.0
FY 1995	305	$ 66.4	76	$42.0	381	$108.4
FY 1996	272	$ 73.7	98	$29.4	370	$103.1
FY 1997	228	$ 72.8	93	$45.8	321	$118.6
FY 1998	177	$ 79.1	104	$56.0	281	$135.1
FY 1999	123	$ 51.7	90	$50.0	213	$101.7
FY 2000	75	$63.9	75	$35.8	150	$99.7
Totals:	2,464	$834.8	692	$313.3	3,156	$1,148.1

The FY 2000 pre-1988 injury award average is $1,348,307 (46 cases).

The FY 1999 pre-1988 injury award average was $855,474 (58 cases).

The FY 2000 post-1988 injury award average is $900,626 (37 cases).

The FY 1999 post-1988 injury award average was $1,433,319 (33 cases).

Awards range up to $8.4 million. The overall pre-1988 injury award average is $827,881.

Awards for death cases are capped at $250,000 plus attorneys' fees/costs.

Return to: Q & A Page || VICP home

For additional information call our public information line at 1-800-338-2382.

10. How many claims have been received by the Program and which vaccines are most commonly involved?

As of April 5, 1999, a total of 5,385 petitions have been filed. The breakdown by vaccine is as follows:

DTP /P/DTP-HIB	71.7%	Tetanus/Td/DT	1.9%
MMR or components	14.5%	New Vaccines	.5%
IPV or OPV	10%	Other*	1.5%

* Vaccine not covered under the Program or unspecified vaccines.

APPENDIX H

MANITOBA PUBLIC INSURANCE CORPORATION ACT, C.C.S.M. c. P215

INDEMNITY	ENTITLEMENT[1]	AMOUNT[2]
1. Income Replacement Indemnity[3] (Division 2)	a) Full time earners (ss. 81-82) - Victim who, at the time of the accident, holds a regular employment on a full time basis but does not include a minor or a student; a minor is under the 16 years of age; a student is 16 years of age or older and attending a secondary or post-secondary educational institution on a full time basis.	Salaried victim - computed on the basis of the gross income[4] derived from his or her employment (or, if the victim proves that (s)he would have held a more remunerative employment but for special circumstances, the indemnity will be calculated on that basis.) Self-employed victim - computed on the basis of the gross income determined in accordance with the regulations for an employment of the same class or the amount the victim earned from his or her work, whichever is greater.

[1]Section 110 stipulates that the entitlement ends when one of the following occurs;
- victim is able to hold employment held prior to the accident;
- victim is able to hold employment granting more remunerative employment;
- victim is able to hold employment determined by the Corporation;
- one year from the day the victim is able to hold employment determined for the victim per ss. 107 or 108;
- victim holds an employment from which the gross income is equal to or greater than the gross income on which the victim's income replacement indemnity is determined;
- the expiration of a time fixed under Subdivision 1;
-victim dies.

Section 117(1) stipulates that if the victim suffers a relapse of the bodily injury within 2 years after the end of the period during which (s)he received an indemnity (other than under ss. 115 or 116) or was not initially entitled to an indemnity, the victim becomes entitled to an income replacement indemnity as though (s)he had been entitled to it from the day of the accident to the day of the relapse. If the relapse occurs more than 2 years later, it will be considered a second accident (ss. 117(3) and 118).

[2]Subdivision 4 - Determination of Indemnity applies to all categories:
The income replacement indemnity is equal to 90% of his or her net income computed on a yearly basis (s.111(1)). The net income is equal to the victim's yearly employment income, to a maximum insurable gross yearly income ($61,500 augmented by a ratio which takes into account increases in the Industrial Average Wage (s.114) less an amount determined in accordance with regulations (s.112(1)): PIPPS Benefits table contained in *Personal Injury Protection Plan: Your guide*, Manitoba Public Insurance Corporation (effective March 1, 2000).

[3]Section 102 provides that a victim receiving an income replacement indemnity ceases to be entitled to it on the later of reaching the age of 65 or five years after the day on which the victim's entitlement commences. The amount is equal to 70% of the victim's net income less pension amounts. If the victim is working and over 65, that person is entitled to income replacement in the same manner, under the same rules, as are claimants under the age of 65.

[4]Gross income includes unemployment insurance benefits or allowances paid under the *National Training Act* R.S.C. 1985, c. N-19.

	b) Temporary Earners and Part Time Earners (ss. 83-84) Part time earner is someone who holds a regular employment on a part time basis but does not include a minor or student; temporary earner is someone who holds a regular employment on a temporary basis but does not include a student or a minor.)	For the first 180 days after the accident - victim is entitled to an indemnity if (s)he is unable to continue the employment or to hold an employment that (s)he would have been able to hold during the period but for the accident or is deprived of employment insurance benefits or allowances paid under the *National Training Act* (NTA). The indemnity is paid for such time as the employment would have been available and for such time as (s)he is unable to hold it or to receive benefits. The amount is computed on the basis of the gross income or the benefits the victim would have received (as per full time earners)
	c) Non-Earners (ss.85-86) Victim who is not employed but who is able to work but does not include a minor or a student.	For the first 180 days - as per temporary and part time earners. As from the 181st day - as per temporary and part-time earners.

	d) Students (ss. 87-92) Victim who is 16 years of age or older and attending a secondary or post secondary educational institution on a full time basis.	Victim is entitled to an indemnity for the time that (s)he is unable, because of the accident, to begin or continue his or her current studies. The entitlement ceases on the day that is scheduled at the time of the accident for the completion of the current studies. The lump sum indemnity for students is as follows: - $7,074 for every school year missed at the secondary level; - $7,074 for every term missed at the post-secondary level to a maximum of $14,147. In addition, the claimant is entitled to receive the greater of: i) an income indemnity as per full time earners; ii) if, after the scheduled date for the completion of his or her studies, the claimant is unable to begin or continue his or her studies and unable to hold employment, the student is entitled to an indemnity computed on the basis of a gross income equal to a yearly average computed on the basis of the Industrial Average Wage;[5] iii) if the victim resumes his or her studies but is unable to hold employment after completing or ending the current studies, the student is entitled to an indemnity from the date of the end of his or her studies and for such time as (s)he remains incapacitated. If the victim's studies end before the scheduled date, (s)he is entitled to: - $7,074 for every school year missed at the secondary level; - $7,074 for every term missed at the post-secondary level to a maximum of $14,147; - an income replacement indemnity calculated on the basis of the Industrial Average Wage.

[5]The Industrial Average Wage as of March 1, 2000 is $544.45 per week, or $28,311.40 per year.

	e) Minors (ss.93-98) Victim who is under 16 years of age.	Victim is entitled to an indemnity for such time as (s)he is unable to begin or complete his or her studies until not later than the end of the school year in which the minor reaches 16 years of age. The amount of the lump sum indemnity is as follows: - $3,818 for every school year missed at the elementary level (maximum); - $7,074 for every school year missed at the secondary level (maximum). In addition, the victim is entitled to the greater of: i) an income replacement indemnity as per full time earners; ii) an indemnity calculated on the basis of a gross income equal to a yearly average computed on the basis of the Industrial Average Wage. This applies to the victim who, from the end of the school year in which (s)he attained the age of 16, is unable to begin or continue his or her studies or hold employment; iii) if the victim resumes his or her studies but is able to hold employment after these studies, (s)he is entitled to an indemnity as follows: - if the studies end before the scheduled date (s)he is entitled to the following amount; - $3,818 for every school year missed at the elementary level; - $7,074 for every school year missed at the secondary level; - from the date scheduled, (s)he is entitled to an income replacement indemnity calculated on the basis of a gross income equal to a yearly average computed on the basis of the Industrial Average Wage.

2. Death Benefits (Division 3)	Victim is a minor and has no dependants on the date of his of her death (ss.123-124)	Each parent is entitled to a lump sum indemnity of $5,614. Funeral expenses are reimbursed to a maximum of $6,120. Grief counselling expenses are reimbursed to a maximum of $2,500.[6]
3. Compensation for Permanent Impairment (Division 4)	Permanent physical or mental impairment (ss. 126-130)	Victim is entitled to a lump sum indemnity of not less than $561 and not more than $112,278.
4. Reimbursement of Expenses (Division 5)	Personal Assistance and various expenses (ss. 131-137)	Victim is reimbursed for expenses of not more than $3,368 per month relating to personal home assistance. Exclusive of expenses covered by social security, a victim may be reimbursed for medical and paramedical care, transportation[7] and lodging for the purposes of receiving such care, purchase of prosthesis or orthopedic devices, cleaning, repair or replacement of clothing the claimant was wearing, and other expenses determined by regulation.
5. Rehabilitation (Division 6)	(s. 138)	Subject to regulation, the Corporation may take any measure it considers necessary or advisable to contribute to the rehabilitation of the victim.

[6]As of June 2000, no regulation has been introduced to codify the entitlement to grief counseling. This award is made pursuant to the initiative of the Manitoba Public Insurance Corporation.

[7]The claimant is entitled to reimbursement for travel at a rate of $0.313 / kilometer to a maximum of 100 kilometers away when similar services are available closer to where the claimant lives.

APPENDIX I

Immunization Protocol for Clients Younger Than 16 Years of Age

New Brunswick

Name: _____ Medicare No.: _____

Date of Birth: _____ Name of parent: _____

Checklist for informed consent (If **shaded** area is not completed at home it must be completed at time of first immunization. **Unshaded** area must be completed at each immunization.)	**Date (yy/mm/dd)**					
Name vaccine(s)† discussed → → →						
The parent is legally capable of giving consent.						
The parent has received verbal information and printed material pertaining to the particular immunization prior to administration. This information included: ☞ The nature and purpose of the vaccine ☞ Risks and benefits of receiving the vaccine ☞ Risks associated with not having the vaccine						
The parent has been informed that it is his/her responsibility to keep personal immunization records up-to-date and easily accessible						
Any questions have been answered and the parent indicated that the information was understood.						
The parent has understood that immunization records shall not be treated as confidential and shall be recorded in an automated system unless otherwise requested.						
Standard pre-immunization questions were asked as per the ***Informed Consent*** policy.						
Vaccines were given according to the recommendations of the Department of Health and Community Services as outlined in the most recent edition of the ***New Brunswick Immunization Handbook.***						
The client was asked to remain for the recommended observation period following the administration of a vaccine.						
Documentation occured immediately following administration.						
The individual accompanying the child was asked to notify Public Health if the vaccinee was unwell within 4 weeks following immunization.						
The necessary reporting and recording of vaccine associated adverse event(s) have occurred.						
Consent has been withdrawn by the parent.						
Nurse's Signature						

† For example: PENTA, MMR, Hep. B, DPT-P, Hib, DT, etc.

35-5140 0697

Immunization Protocol for Clients 16 Years of Age or Older

New Brunswick

Name: _____ Medicare No.: _____

Date of Birth: _____

Checklist for informed consent	Date (yy/mm/dd)					
Vaccine → → →						
The client determined to be legally capable of giving consent.						
The client has received verbal information and printed material pertaining to the particular immunization prior to administration. This information included: ☞ The nature and purpose of the vaccine ☞ Risks and benefits of receiving the vaccine ☞ Risks associated with not having the vaccine						
The client was informed that it is his/her responsibility to keep personal immunization records up-to-date and easily accessible.						
Any questions have been answered and the client indicated that the information was understood.						
The client has understood that immunization records shall not be treated as confidential and shall be recorded in an automated system unless otherwise requested.						
The client's health was assessed.						
Vaccines were given according to the recommendations of the Department of Health and Community Services as outlined in the most recent edition of the ***New Brunswick Immunization Handbook.***						
The client was asked to remain for the recommended observation period following the administration of a vaccine.						
Documentation occured immediately following administration.						
The client was asked to notify Public Health if they were unwell within 4 weeks following immunization.						
The necessary reporting and recording of vaccine associated adverse event(s) have occurred.						
Nurse's Signature:						

35-5142 0697

EXECUTIVE SUMMARY OF REPORT ON

COMPENSATION OF VACCINE-DAMAGED CHILDREN

EXECUTIVE SUMMARY

A. INTRODUCTION

This project was initiated by a member of the Commission and in response to a request from the Association for Vaccine-Damaged Children.

Routine childhood immunization is a cornerstone of public health practice in Canada. It has received the strong support of government, the medical profession and the great majority of the public. It has achieved much success in the reduction of many childhood illnesses including polio, diphtheria, whooping cough, mumps and measles.

A vaccine should confer long-lasting protection against disease, be administered in few doses, be inexpensive enough for wide-scale use, be stable enough to remain potent during shipping and storage and have *no adverse effect on the recipient*. This Report deals with the failure to achieve fully the last of these objectives. In spite of the efforts of medical science, manufacturers and physicians, vaccines sometimes have side effects and adverse consequences may be suffered by the recipients of vaccines.

The extent to which vaccines cause serious adverse consequences is, however, a matter of considerable debate both inside and outside the medical profession. The situation is further complicated by both the difficulty in distinguishing between conditions that are *temporally related* to the administration of the vaccine and conditions that are *caused* by the vaccine and by the fact that the system of routine childhood vaccination is not static. New vaccines are periodically introduced and old vaccines are replaced with improved products.

The purpose of this Report is to make recommendations in respect of the compensation of children who can establish that they *have* suffered serious, adverse consequences as a result of a vaccination or a series of vaccinations. It will be shown that the existing public and private vehicles for the compensation of personal injury are insufficient to provide the financial support needed by those who suffer rare but serious consequences. Special measures are needed to support and assist them.

The debate about the extent and seriousness of adverse vaccine consequences is one that this Report does not enter. It is beyond the expertise and resources of the Manitoba Law Reform Commission even to comment on it, let alone resolve it.

B. THE CURRENT LAW

It is a fundamental axiom of the common law of torts that a person is liable in damages for death or injury caused by his or her fault. Consequently, children who have been injured by the administration of a vaccine may sue any person (health care professional, vaccine manufacturer or governmental agency) if it can be proven on the balance of probabilities that the injuries were caused by that person's fault. This compensatory remedy is, however, more theoretical than real. Vaccine-damaged children face such difficulties in establishing the negligence of a defendant and the causal link between the negligence of the defendant and the plaintiff's losses that we are not aware of any case in Canada where a vaccine-damaged child has sued successfully. Some governmental support is available to these children from established programs. Medical treatment is free of charge, pharmaceutical costs are subsidized and some tax benefits are given for extra medical expenses. Social allowances are available to the destitute. Charitable organizations may provide some assistance. In the Commission's view, the current accident compensation system in Manitoba is inadequate to the needs of vaccine-damaged children.

C. VACCINE COMPENSATION SCHEMES IN OTHER JURISDICTIONS

Many jurisdictions throughout the world have introduced special compensatory initiatives to address vaccine-related injury and illness. Consideration is given to only four of them: Québec (the only province in Canada to have such a scheme), the United States, and the two other common law jurisdictions with compensatory schemes, the United Kingdom and New Zealand. The Commission reviews these various schemes including the vaccines covered, compensable injuries, the compensation awarded, procedures and appeals, funding, limitations, tort claims, retroactive claims and the claims experience in each jurisdiction.

D. RECOMMENDATIONS FOR A MANITOBA CHILDHOOD VACCINATION INJURY COMPENSATION PLAN

The Commission recommends that a discrete no-fault compensation plan, funded by the provincial government, be established to cover past and future vaccine-damaged children. A special initiative is warranted not only by the plight of seriously injured children but also by the fact that the provincial childhood immunization program is heavily promoted by government; it is for the benefit of the whole community and the consent to vaccination is a substitute consent given by parents in the interests of their children. The Reports contains the broad principles on which a compensation plan should operate. The current financial constraints of the Commission prevent it from providing a draft Act or formulating the details and policies for the implementation of these recommendations. To the extent possible, the Commission recommends that use be made of existing programs as models for the implementation of these recommendations. The central recommendation is that Manitoba establish a no-fault compensation plan to cover all children who

have suffered a real possibility that the adverse consequences were caused by a vaccination. It is further recommended that the compensation payable be equivalent to that paid under the Personal Injury Protection Plan of Autopac to a child injured in a motor vehicle accident. The Manitoba Childhood Vaccination Injury Compensation Plan would be established within Manitoba Health. The Commission recommends that the claims procedure and appeal structure be modeled on the way compensation claims of the victims of criminal violence are handled under *The Victims' Rights Act*. The recommendations do not include any restriction on the right of vaccine-damaged children to sue in tort.

The Commission also recommends that Manitoba Health and all health related professional associations introduce initiatives to increase public understanding of the risks and benefits of childhood immunization and thereby increase confidence in the process. It further recommends that Manitoba Health and health care professional associations take all steps necessary to promote the full and complete reporting of all adverse events temporally associated with vaccines.

RÉSUMÉ

DU RAPPORT SUR L'INDEMNISATION DES ENFANTS AYANT SUBI DES DOMMAGES CORPORELS ATTRIBUÉS À LA VACCINATION

RÉSUMÉ

A. INTRODUCTION

Le présent projet a été amorcé par un membre de la Commission de réforme du droit du Manitoba à la suite d'une demande de la Association for Vaccine-Damaged Children.

L'immunisation systématique des enfants est une pierre angulaire du système canadien de santé publique. Elle a reçu l'appui massif des gouvernements, des professions médicales et d'une forte majorité du public. Grâce à l'immunisation systématique, le Canada a largement réussi à réduire les maladies d'enfance telles que la polio, la diphtérie, la coqueluche, les oreillons et la rougeole.

Un vaccin devrait conférer une protection durable contre la maladie, être administré en un faible nombre de doses, être suffisamment peu coûteux pour en permettre l'utilisation générale, être assez stable pour conserver sa puissance au cours de la livraison et l'entreposage, et n'exercer *aucun effet indésirable sur le receveur*. Le présent rapport traite du défaut d'atteindre pleinement le dernier de ces objectifs. En dépit des efforts des sciences médicales, des fabricants et des médecins, il arrive que des vaccins aient parfois des effets secondaires et que les receveurs du vaccin puissent en subir des conséquences négatives.

Cependant, le degré des conséquences négatives sérieuses que causent les vaccins fait l'objet de grandes discussions tant à l'intérieur qu'à l'extérieur des professions médicales. La situation se complique davantage en raison de la difficulté à distinguer les conditions qui sont *temporairement liées* à l'administration d'un vaccin de celles qui sont *causées* par le vaccin, et du fait que le système d'immunisation systématique des enfants n'est pas statique. L'introduction de nouveaux vaccins se fait périodiquement et de vieux vaccins sont remplacés par des produits améliorés.

Le présent rapport a pour objet de faire des recommandations en ce qui concerne l'indemnisation des enfants qui peuvent déterminer qu'ils ont *effectivement* subi des conséquences négatives sérieuses provoquées par une vaccination ou une série de vaccinations. Il sera démontré que les organes existants de compensation publics et privés en cas de préjudices corporels sont insuffisants quant à la prestation de l'aide financière dont ont besoin ceux qui souffrent de conséquences rares mais tout de même sérieuses. Il importe de prendre des mesures spéciales pour les appuyer et les aider.

Ce rapport ne tient pas compte du degré et de la gravité des conséquences négatives des vaccins. Il dépasse l'expertise et les ressources de la Commission de réforme du droit du Manitoba d'offrir un avis sur ces questions et, à plus forte raison, de les résoudre.

B. LA LOI ACTUELLE

L'un des principes de base du droit de la responsabilité civile délictuelle de la common law stipule qu'un individu est passible de dommages-intérêts dans le cas du décès ou de la blessure dont il est responsable. Par conséquent, les enfants ayant subi une blessure à la suite de l'administration d'un vaccin ont le droit d'exercer une poursuite civile contre toute personne, p. ex., professionnel de la santé, fabricant de vaccin ou organisme gouvernemental, si l'on peut prouver selon toute probabilité que les blessures ont été causées par la faute de cette personne. Toutefois, cette voie de recours compensatoire est davantage théorique que réelle. Puisque les enfants ayant subi des dommages corporels attribués à la vaccination se heurtent à de très grandes difficultés à établir la négligence de la part de l'accusé ainsi que le lien de causalité entre la négligence de l'accusé et les pertes subies par le demandeur, nous ne connaissons aucun cas au Canada où un enfant ayant subi des dommages corporels attribués à la vaccination n'a pu intenter avec succès une action en justice contre qui que ce soit. Les gouvernements accordent à ces enfants une certaine mesure d'aide financière en vertu des programmes établis. Les soins médicaux sont offerts sans frais, les frais pharmaceutiques sont subventionnés et certains avantages fiscaux sont accordés pour des frais médicaux additionnels. Pour leur part, les personnes privées de ressources ont droit à une aide sociale. De plus, les associations de bienfaisance peuvent être en mesure d'offir de l'aide. La Commission est de l'avis que le système d'indemnité d'accident actuellement en vigueur au Manitoba ne satisfait pas adéquatement aux besoins des enfants ayant subi des dommages corporels attribués à la vaccination.

C. RÉGIMES D'INDEMNISATION EN VIGUEUR DANS D'AUTRES TERRITOIRES

Plusieurs territoires à travers le monde ont mis en oeuvre des initiatives d'indemnité spéciale visant les blessures et les maladies liées à l'administration de vaccins. La Commission n'a considéré que quatre de ces territoires : le Québec (la seule province canadienne ayant adopté un tel régime), les États-Unis, et deux autres pays de common law, soit le Royaume-Uni et la Nouvelle-Zélande. La Commission passe en revue, pour chacun des territoires, les vaccins admissibles, les préjudices compensables, l'attribution des indemnités, les procédures et les appels, le financement, les restrictions, les réclamations en responsabilité civile délictuelle, les réclamations rétroactives et les dossiers d'indemnité.

D. RECOMMANDATIONS RELATIVES À UN RÉGIME MANITOBAIN D'INDEMNISATION DES ENFANTS AYANT SUBI DES DOMMAGES CORPORELS ATTRIBUÉS À LA VACCINATION

La Commission recommande l'instauration d'un régime distinct d'indemnisation hors-faute, financé par le gouvernement provincial, pour les enfants ayant subi des dommages corporels attribués à la vaccination par le passé ou à l'avenir. Une telle initiative spéciale est justifiée non seulement par la situation des enfants gravement blessés mais aussi par le fait que le programme

provincial d'immunisation des enfants fait l'objet d'une promotion agressive de la part du gouvernement. De plus, un régime d'indemnisation serait appliqué au profit de la collectivité entière. Le consentement à la vaccination par les parents est donné au nom de leurs enfants et dans l'intérêt de ces derniers. Le rapport fait état des principes généraux sur lesquels se fonderait un régime d'indemnisation. Les contraintes financières auxquelles fait face la Commission l'empêchent de rédiger un projet de loi et d'élaborer les détails ainsi que les politiques relativement à la mise en oeuvre de ces recommandations. Ainsi, la Commission recommande que les programmes existants servent dans la mesure du possible de modèles de mise en oeuvre des recommandations de ce rapport. La principale recommandation vise l'établissement d'un régime manitobain d'indemnisation hors-faute qui couvrirait tous les enfants qui font face à la possibilité réelle de conséquences négatives à la suite d'une vaccination. Il est également recommandé que l'indemnisation exigible soit équivalente à celle qui est payée à un enfant victime d'un accident de véhicule automobile en vertu du Régime de protection contre les préjudices personnels d'Autopac. Le régime manitobain d'indemnisation des enfants ayant subi des dommages corporels attribués à la vaccination serait mis en oeuvre au sein du ministère de la Santé du Manitoba. La Commission recommande que la procédure de demandes d'indemnités et la structure des réclamations suivent le modèle de gestion des demandes d'indemnisation des victimes de violence criminelle en vertu de la *Loi sur les droits des victimes*. Les recommandations ne comprennent aucune restriction relative aux droits des enfants ayant subi des dommages corporels attribués à la vaccination d'intenter une action en responsabilité délictuelle.

La Commission de réforme du droit recommande également que le ministère de la Santé du Manitoba et toutes les associations professionnelles de la santé présentent des initiatives visant à sensibiliser davantage le public aux risques et aux avantages de l'immunisation des enfants, ce qui permettrait d'accroître la confiance du public dans le processus. Elle recommande enfin que Santé Manitoba et les associations professionnelles de la santé fassent le nécessaire pour promouvoir la pleine et entière déclaration des réactions négatives qui sont temporairement associées à la vaccination.